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OFFICIAL TRANSCRIPT

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Before the

UNITED STATES
DEPARTMENT OF AGRICULTURE

In the Matter of:

ADVISORY COMMITTEE ON MEAT AND
POULTRY INSPECTION

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11 Thursday, July 29, 1982

12 Volume I

13
14 The above-entitled matter came on for public
15 hearing at 1:00 p.m.

16 BEFORE:

17 DR. DONALD L. HOUSTON
18 Administrator
19 Food Safety and Inspection Service
USDA

20 ROBERT G. HIBBERT
21 Director
22 Standards and Labeling Division
Food Safety and Inspection Service, USDA

23 D. C. BREEDEN, Acting Regional Director
24 Western Region, MPI
25 Food Safety and Inspection Service
USDA

1 MEMBERS OF THE ADVISORY COMMITTEE
2 ON MEAT AND POULTRY INSPECTION

3
4 Dr. Roslyn B. Alfin-Slater
5 School of Public Health
6 University of California
7 Los Angeles, CA 90024

8
9 Dr. Carroll S. Brickenkamp
10 National Bureau of Standards
11 U.S. Department of Commerce
12 Washington, D.C. 20234

13 Dr. Mahlon Burnette
14 Executive Director
15 The League for International
16 Food Education
17 Suite 915
18 915 Fifteenth Street, N.W.
19 Washington, D.C. 20005

20 Honorable S. Mason Carbaugh
21 Commissioner of Agriculture
22 and Consumer Services
23 Commonwealth of Virginia
24 Richmond, VA 22309

25 Dr. Frank R. Craig
26 Director of Health Services
27 Perdue Farms, Inc.
28 Salisbury, MD 21801

29 Mrs. Ester Cramer
30 Vice President, Community Relations
31 Alpha Beta Company
32 777 South Harbor Boulevard
33 La Habra, CA 90631

34 Professor E. M. Foster
35 Director, Food Research Institute
36 and Chairman, Department of Food
37 Microbiology and Toxicology
38 University of Wisconsin
39 Madison, WI 53706

1 Honorable Robert H. Lounsherry
2 Secretary
3 Department of Agriculture
State of Iowa
Des Moines, IA 50310

4 Mr. John E. McDade
Executive Vice President
5 Norbest, Inc.
P. O. Box 1529
6 Salt Lake City, UT 84110

7 Ms. Rosemary Mucklow
Executive Vice President
8 Western States Meat Association
88 First Street
9 San Francisco, CA 94103

10 Honorable Dean Pridgeon
Director
11 Department of Michigan
Lansing, MI 48909

12 Dr. Ernest Ross
13 Poultry Scientist
14 Department of Animal Sciences
University of Hawaii
1800 East-West Road
15 Honolulu, HI 96822

16 Honorable Keith Sebelius (Not Present)
17 Attorney and former Member of Congress
602 West Wilberforce Street
Norton, KS 67654

18 Ms. Yvonne Vizzier
19 Assistant Vice President
Marshal Durbin Companies
20 541 Ford Avenue
Jackson, MS 39209

21 Mr. William D. Waters
22 Pork Producer
Stillwaters, Inc.
23 Route 1, box 90
Palmyra, NC 27859

24

25

1 Dr. Elizabeth Whelan
2 Executive Director
3 American Council on Science
and Health
4 1995 Broadway
New York, NY 10023

5 Dr. George D. Wilson
6 Vice President, Scientific Affairs
American Meat Institute
7 1700 North Moore Street
Arlington, VA 22209

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1 THURSDAY, July 29, 1982

(1:00 P.M.)

2 P R O C E E D I N G S

3 DR. HOUSTON: Welcome to San Francisco.

4 My name is Don Houston and I'm the Administrator
5 of the Food Safety and Inspection Service and the Vice-Chairman
6 of the Advisory Committee on Meat and Poultry Inspection.

7 With me today to my right is Mr. Bob Hibbert,
8 Director of our Standards and Labeling Division. To my left
9 is Dr. Don Breeden, the Regional Director for the Western
10 Region, Food Safety and Inspection Service.

11 I understand most of you were able to participate
12 this morning in the plant tour. Some of you went to the Gallo
13 operation; others I understand went to the San Francisco
14 Sausage Company. I'm hearing many good reports that you
15 enjoyed the opportunity to see those kinds of operations.

16 I want to thank the Western States Meat Associa-
17 tion for arranging for that tour and for working with our own
18 Regional Office here in setting up the arrangements for
19 transportation. So for those of you from the
20 Western States Meat Association, we are grateful for that.

21 MS. MUCKLOW: You're most welcome.

22 DR. HOUSTON: We have several new members with us
23 that were not with us when we had the first meeting of this
24 newly chartered Committee.

25 With us today is Dr. Roslyn B. Alfin-Slater. Dr.

1 Alfin-Slater is a Professor of Biochemistry at the School of
2 Public Health, University of California, Los Angeles. She is
3 the author of over 170 publications including many numerous
4 scientific books and journals, is the member of many scientific
5 and educational associations and government committees, and is
6 recognized for her outstanding achievements in scientific
7 research. Dr. Alfin-Slater is to my right.

8 Dr. Mike Foster, a long time friend, is Director of
9 the Food Research Institute and Chairman of the Department of
10 Food Microbiology and Toxicology at the University of Wisconsin.
11 He has served and continues to serve on numerous task forces and
12 advisory committees concerned with food microbiology and food
13 safety. He is recognized as an expert on food hygiene and has
14 served on several occasions as consultant to the National
15 Academy of Sciences, F.D.A., U.S.D.A., the Atomic Energy
16 Commission, and the World Health Organization.

17 Also with us today, a new member, is Mr. Robert H.
18 Lounsberry. Bob Lounsberry is the Secretary of Agriculture for
19 the State of Iowa. He was elected to his current position in
20 1972, reelected in 1974, and again in 1978. Until 1970,
21 Mr. Lounsberry ran a livestock and grain operation in Iowa. He
22 is the former President of the Midwest Association of State
23 Departments of Agriculture, and has been a member of numerous
24 educational and agriculture organizations. He is known as a
25 leader in American agriculture.

1 Dr. Elizabeth Whelan is the Executive Director of
2 the American Council on Science and Health with offices in New
3 York and New Jersey. She is the author of many books and
4 articles on nutrition and health, is a radio commentator on
5 health issues, and moderator of a nationally syndicated
6 radio program. Dr. Whelan has appeared on the TODAY SHOW,
7 GOOD MORNING, AMERICA, and other national media programs. She
8 is a member of the Nominating Committee of the American Cancer
9 Society, and the Board of Directors of the Food and Drug Law
10 Institute.

11 We do have a full complement of the Committee here
12 today so perhaps San Francisco does have some drawing power.
13 I welcome all of you and I think you very much for coming. A
14 special welcome to our members who are able to be with us for
15 the first time.

16 I'm not going to go over the role of the Advisory
17 Committee. We went into that subject in great detail at the
18 first meeting. However, since we do have several new members
19 with us today, I have asked the staff to provide you with
20 documentation on the role of the Committee. You can peruse
21 that at your convenience.

22 Last time when we were together we covered several
23 subjects and I might be able to give you a quick update on them
24 before we get into today's agenda.

25 We talked about the interstate shipment of state

1 inspected product. Since that time there has been a Bill
2 introduced in the House by Congressman Wampler and in the
3 Senate by Senator Inouye.

4 The Administration position on that Bill was
5 delivered to the Congress last week. We are supporting that
6 Bill, as we indicated we would at the time we met with you
7 last.

8 There has been no new indication at this point of
9 either the House or the Senate holding hearings on that Bill.
10 Obviously we are in support of it, and we will be working with
11 those groups who are interested in having hearings.

12 We recently met with the National Association of
13 State Departments of Agriculture, who indicated a strong
14 interest in seeing action on the Bill. We'll have to see what
15 develops over the next few months.

16 We talked about Food Safety Reform. I won't go
17 into that since that's on today's agenda. We'll be talking
18 about that in more detail.

19 We talked about an exemption study which was under-
20 way and I will simply say that the study is continuing along
21 the lines that we discussed at the last meeting, and that it
22 should be ready sometime this fall.

23 We talked about a fee for service program for
24 meat and poultry inspection. To bring you up-to-date,
25 the 1983 budget for meat and poultry inspection does not

1 contain any user fees; however, I would say that there was
2 serious consideration given to that prior to the time that the
3 budget was sent to the Congress. The Office of Management and
4 Budget did direct the Department to conduct a very compre-
5 hensive study on user fees and their applicability to funding
6 the federal meat and poultry inspection program. That study
7 has been completed and has not yet been made public. I'm sure
8 that it will be sent along to the Office of Management
9 and Budget when the budget proposals for 1984 go forward, which
10 will be sometime in September.

11 We talked also about modifying the continuous
12 inspection provisions of the Federal Meat Inspection Act and
13 Poultry Products Inspection Act. We will be discussing that
14 further in these meetings, so I will pass over that for the
15 time being.

16 We also talked about the Administration's initia-
17 tives in the area of restricting sodium intake through
18 moderating the dietary intake of sodium. That is also on the
19 agenda and I will wait until we get to that point.

20 We discussed the standard for braunschweiger. That
21 is still under consideration and no final action has yet taken
22 place.

23 We talked about a standard for what was then called
24 mechanically processed species product. Since that time the
25 Department has promulgated a final rule renaming that product

1 mechanically separated meat. It has been called mechanically
2 deboned meat in the industry for many years. That standard
3 will go into effect July 29th, today I think.

4 However, several days ago, perhaps a week ago, the
5 Community Nutrition Institute in conjunction with the Consumer
6 Federation of America, Americans for Democratic Action, and
7 Virginia Citizens Consumer Council brought suit against the
8 Department to have that standard set aside. They are asking
9 for an expedited review, and arguments to that effect will
10 take place tomorrow in a Washington, D.C., Federal District Court.

11 The Government will be arguing that an expedited
12 review is not necessary and that time should be taken
13 so that all of the points of the case can be considered on
14 their merit.

15 So the standard will go into effect today, but I
16 doubt that there'll be much attempt by industry to utilize
17 that product until this litigation is settled.

18 I would add also that a press release which was
19 issued yesterday in Washington by the Center for Science in
20 the Public Interest has asked for the resignation of Secretary
21 Block for, among other things, revising the standard for
22 mechanically separated meat.

23 My purpose here is not to necessarily give
24 publicity to the Center for Science in the Public Interest and
25 their request for the resignation of Mr. Block, but I do point

1 out to you that the subject of mechanically separated meat
2 remains one of controversy.

3 To those of you who are interested in the press
4 release that was issued on that matter as well as the letter
5 that was delivered to the Secretary on July 28th, I have them
6 and if you'd like to look at them, I'll be glad to share them
7 with you.

8 Before I move on to today's agenda, are there any
9 questions about any of those areas that some of you would like
10 to raise at this point?

11 Dr. Alfin-Slater.

12 DR. ALFIN-SLATER: I would like to know why every-
13 thing that Michael Jacobsen says gets so much publicity in the
14 press, and why people consider this man seriously when he
15 should not be taken seriously? When he wants something set
16 aside, or the Community Nutrition Institute, what reasons do
17 they give?

18 Do they give valid reasons? Who is there to rebut?

19 DR. HOUSTON: Well, as you know there are a number
20 of consumer activist groups in Washington, some of which I
21 mentioned in the lawsuit. For reasons that are probably better
22 explained by them, they have good contacts with the press and
23 are able to get that kind of attention.

24 I did not read to you all of the points that are
25 raised in the press release. They go beyond just what was

1 mentioned with regard to mechanically separated meat.

2 As you know the political climate is starting to
3 heat up for the elections this fall. I think we can expect
4 more and more rhetoric in a number of areas.

5 Rosemary.

6 MS. MUCKLOW: This is Rosemary Mucklow. Just for
7 the record, Don, I would like to add that the Western States
8 Meat Association and the American Meat Institute have filed a
9 petition to intervene in the action brought by the Community
10 Nutrition Institute against the United States Department of
11 Agriculture, and our Washington counsel will be present at the
12 status conference tomorrow when some determinations will
13 hopefully come out with respect to the program and the
14 expedited hearing or non-expedited hearing of that action.

15 DR. HOUSTON: Any other questions on those points?

16 In addition to those items I mentioned that would
17 be on today's agenda, we will also be talking about the
18 Margarine Standard, the Prior Labeling Approval System, the
19 inspection of imported meat and poultry, and finally some com-
20 ments on food safety education.

21 Our operating procedures for the Committee will
22 remain as they have in the past. In order to broaden the
23 understanding of Committee members on the various subjects,
24 those of us here at this table will be making presentations
25 today. Following those presentations we would ask you to limit

1 your comments to those of questions of clarification. We're
2 hoping that by doing this we can get through the entire agenda
3 and then have tomorrow for some discussion by, among and
4 between the various members of the Advisory Committee.

5 If any of you cannot make tomorrow's meeting and
6 wish to make some remarks and put them on the record, we'd
7 be glad to have you do that. But if you're going to be here
8 tomorrow, we would request that you hold off any discussions on
9 policy and substance until that time, and to limit comments
10 and questions to those of clarification.

11 This is a public meeting and it will be covered
12 by the press. Since it is a public meeting, we will offer an
13 opportunity today at the end of the session for anyone in the
14 audience who wishes to raise a question, who wishes to make a
15 statement, to do so. We will offer that same opportunity
16 tomorrow at the end of that session.

17 Before we go into today's presentations, are there
18 any questions on the agenda?

19 Let's get into the items to be discussed. The
20 first item is the Margarine Standard, and Mr. Hibbert will be
21 covering that.

22 I would remind the Committee that one of the
23 reasons that we do discuss standards is that by law we can-
24 not promulgate or revise a food standard unless there does
25 exist consultation with members of this Committee.

1 THE MARGARINE STANDARD

2 The Margarine Standard is being revised to bring it
3 up-to-date with modern food processing technology and to be sure
4 it's in line with the standards that have been established by
5 F.D.A. I would not suggest that this is a major issue, cer-
6 tainly not a controversial issue. To a large extent this is a
7 housekeeping exercise so that we can make these changes and
8 meet the legal requirements of consulting with this Committee.

9 After we get through with two or three of these
10 topics, then we'll take a break about midafternoon.

11 Bob, do you want to go ahead.

12 MR. HIBBERT: Thank you. It's nice to be here.
13 Hopefully with that introduction you're all on the edge of
14 your chairs about the Margarine Standard.

15 It is, as Dr. Houston pointed out, essentially a
16 housekeeping measure for us. It is not an area of great
17 controversy, although it obviously is of some significance if
18 you're in the margarine business, and obviously within that
19 relatively narrow universe there are some strong points of
20 view on a few of these issues.

21 In addition, this may be of interest
22 to some of you who are interested in food standards generally
23 and how they are made and what some of the kinds of problems
24 are, because some of the problems we encounter here crop up
25 in all of our standards work.

1 (The first slide was shown to the Committee.)

2 This first slide provides you with a general kind
3 of definition to get oriented with the product, which is used
4 in our regulations and those of the Food and Drug Adminis-
5 tration, that being that margarine is food in plastic form or
6 liquid emulsion containing not less than 80 percent fat and
7 certain required and optional ingredients.

8 Now in our area the key ingredient that makes a
9 jurisdictional difference is the use of animal fats versus
10 other kinds of oils. If animal fats are used, it is a product
11 under our jurisdiction and is regulated under our system,
12 inspected as such, and we control the standards.

13 The basis thrust of this proposal is to eliminate
14 unnecessary discrepancies with regulation by the F.D.A. About
15 97 percent of the margarine marketed is an F.D.A. product.
16 Our products are about 2 or 3 percent.

17 (The next slide was shown to the Committee.)

18 Our proposed standard, which was issued on the
19 20th of July, specifies required ingredients, and this is of
20 general interest again for food standards. Basically, we're
21 talking about what you have to have in something to, in effect,
22 meet the basic eligibility requirements or standard, and then
23 what can you also put in and not get outside the standard again.

24 In terms of required ingredients you have to have
25 edible fats or oils, in addition to Vitamin A.

1 The vitamin A requirement is one of long standing, both
2 with us and Food and Drug Administration, and flows from the
3 fact that butter is a major source of Vitamin A in the diet.
4 Vitamin A is a required ingredient, in addition to one or more
5 of the following ingredients: water, milk or milk products,
6 or vegetable proteins.

7 (The next slide was shown to the Committee.)

8 The next slide just delineates some of the optional
9 ingredients. When I touch upon the comments briefly you'll
10 see that we get into some area of controversy here.

11 In our proposal we specified the following as
12 optional ingredients: nutritive carbohydrate sweeteners,
13 emulsifiers, preservatives, antioxidants, color additives,
14 beta-carotene, and potassium chloride.

15 (The next slide was shown to the Committee.)

16 Now for comparative purposes I just pulled out the
17 Food and Drug Administration Standard, and essentially it
18 indicates that Standards parallel each other with the following
19 exceptions: under the F.D.A. Standard there's a more general
20 authorization for sweeteners, for emulsifiers, preservatives
21 including antioxidants, color additives, there's some dis-
22 tinctions on special labeling of flavors, and there is a
23 general statement in their Standard to the effect that the
24 product only contain safe and suitable ingredients.

25 Now, what we get into here is essentially a

1 mechanical distinction from the way we operate and Food and
2 Drug operates.

3 We have more of an affirmative listing system for
4 food ingredients, food additives than does F.D.A. They use
5 concepts such as safe and suitable in their Standards; we as
6 a general rule do not, but will specify in our regulations
7 specific substances within a class such as antioxidants,
8 emulsifiers, whatever, whereas F.D.A. is more inclined to use
9 general language.

10 DR. ALFIN-SLATER: Do they define what they mean
11 by suitable ingredients?

12 MR. HIBBERT: That's a term which has evolved in
13 their system and I think it's been interpreted in case law and
14 discussed in various regulations. Essentially it works its
15 way back to the F.D.A. categorization scheme in determining
16 whether substance has GRAS status or is GRAS affirmed, so on
17 and so on.

18 It gets back to their whole additive review system.

19 DR. ALFIN-SLATER: I understand the safe, but I
20 don't know what is meant by suitable.

21 MR. HIBBERT: I think suitable gets more into
22 concepts of good manufacturing practice and things of that
23 nature, and having a function, have an actual efficacy kind
24 of function in a product. You have to make some demonstration
25 that you need to emulsify in order to use an emulsifier.

1 (The next slide was shown to the Committee.)

2 The comments, as I indicated, were from a relatively
3 narrow audience. We received, I believe, 14 comments. The
4 process was focused upon, if you will, by the National Margarine
5 Association. They supplied the most detailed comment.

6 A number of the comments simply indicated support
7 for the National Margarine Association's position.

8 As you can see from what I've delineated out of
9 the comments, this question of our affirmative listing versus
10 the F.D.A.'s concept is really the problem, that
11 came out in the comments. We simply need to analyze and take
12 a position on in the final rule.

13 They would prefer, since again they are 97 percent
14 of the way into the F.D.A. scheme of things,
15 that we would adopt the concept such as safe and suitable.
16 In addition to that, they addressed some specific substances.
17 The first, Vitamin E, is not allowed under the current F.D.A.
18 Standard or our proposed Standard. That is an item of some
19 controversy in the Margarine rule. The current Codex Standard
20 permits the use of Vitamin E. The United States position
21 which we in Food and Drug have maintained over the years, has
22 been that fortification with Vitamin E is not necessary in this
23 country.

24 Again they focused on fructose as a sweetener that
25 we did not specify in our proposal which they would want to be

1 specifically permitted.

2 They wanted an elimination of the proposed maximum
3 levels for various emulsifiers. That is, we proposed in synch
4 pending with F.D.A. to raise that limit. Obviously, our
5 analysis of the issue would be considered in that context.

6 Again, back to this umbrella concept issue, they
7 asked for a wider variety of acidulants and alkalizers. They
8 also had problems with a labeling point which I think can be
9 cleared up, but our proposal can be read to require the entire
10 spelling out of the substances BHA and BHT. We do not currently
11 require that, but the proposal could probably fairly be read
12 as if we were intending to impose their requirement. They had
13 some reservations about that. The F.D.A. does not require people
14 to do that, either.

15 That's essentially it for the Margarine Standard.
16 I'd be happy to answer any clarifying questions.

17 DR. ALFIN-SLATER: I have another question. When
18 you prepare something from vegetable oil, vegetable oils con-
19 tain Vitamin E, normally and naturally. Why is there a
20 problem about adding it?

21 Are the oils stripped of the Vitamin E before they
22 are hydrogenated?

23 MR. HIBBERT: My understanding is that it's more of
24 a question that it gets into general questions of fortification
25 policy. Obviously the processing may have varying effects on

1 vitamins, but it is not the position of either us or F.D.A. at
2 this point that there is such a need for Vitamin E in the diet
3 that it should be supplied through an unnatural process such
4 as fortification of this particular product.

5 DR. ALFIN-SLATER: It's an antioxidant that pre-
6 vents oxidation of the essential fatty acids which are in the
7 vegetable oil.

8 DR. BURNETTE: I think when they bleach vegetable
9 oils that there wouldn't be very much Vitamin E left in there,
10 naturally.

11 DR. ALFIN-SLATER: It would be nice if we had an
12 analysis available because I have a feeling there's a lot more
13 left than you think, unless the oil is stripped for some other
14 purpose and the Vitamin E removed for some other purpose. I
15 don't know.

16 DR. BURNETTE: It's stripped when it's bleached to
17 be clarified so you get a clear vegetable oil. There's not
18 much left in there; it's a rather vigorous process.

19 DR. HOUSTON: Are there any other questions?

20 DR. BURNETTE: Bob, what's the status of the Codex
21 Alimentarius Standard for Margarine? Is it approved, or is it
22 still in the steps?

23 MR. HIBBERT: It's somewhere in the steps. I have
24 a copy of it with me. Maybe I should check later, but it has
25 not been formally adopted.

1 DR. BURNETTE: It's up about six or seven?

2 MR. HIBBERT: I believe that's correct but I can
3 clarify that point for you a little later.

4 DR. BURNETTE: Your proposal, or at least the half
5 of the proposal that we got, mentions the Codex Alimentary
6 Standard but doesn't make any comparison such as you just did
7 with the F.D.A. Standard. Since by Treaty we're going to have
8 to consider the Codex Standard when it passes in this
9 country, can you give us a comparison of how the F.D.A. or
10 F.D.A./U.S.D.A. Standard compares? Are we going to have to do
11 this all over again in another couple years?

12 MR. HIBBERT: I think the basic distinction is the
13 question of Vitamin E. That's what the commentors have
14 focused on. There may very well be some other nuances as well.

15 DR. BURNETTE: Do you think the rest of the
16 Standard as proposed fairly well tracks Codex Alimentary
17 Standard?

18 MR. HIBBERT: Well, I wouldn't go that far. I
19 think that there may be some additional restrictions in ours
20 as well with regard to certain substances. But I can't answer
21 these questions past a certain point. I don't have that good
22 a feel for the Codex Standard myself.

23 DR. BURNETTE: Well, it's just that when it comes
24 out, we're required by Treaty to consider it. It seems to me
25 that should be considered at this point. There's no need in

1 doing it twice, three times actually.

2 DR. HOUSTON: That's true, but considering the fact
3 that the F.D.A. Standard has been set and they are not in
4 rule-making at this time, I think we would
5 have to consider how much risk we want to take in determining
6 whether or not we are going to come into line with the Codex
7 Standard; and whether we want to go that far with Vitamin E
8 and some of the other changes to permit a broader variety of
9 acidulants, emulsifiers, etc., that I'm sure are under the
10 Codex Standard. Usually they're much broader than ours, as
11 you well know.

12 MR. HIBBERT: I've got more specificity here.

13 Basically the Codex Standard parallels what we've
14 proposed but permits Vitamin E fortification, allows additional
15 color additives, allows additional classes of emulsifiers at
16 higher levels, temporarily endorses a variety of antioxidants,
17 and allows the use of natural and synthetic topherol.

18 Those are the basic distinctions.

19 DR. BURNETTE: Thank you.

20 DR. HOUSTON: Are there any other questions of
21 clarification?

22 PRIOR LABELING APPROVAL SYSTEM

23 If not, let's move to the next item on the agenda,
24 which is near and dear to the hearts of meat and poultry
25 processors everywhere, the Prior Labeling Approval System,

1 carried out by the Department of Agriculture.

2 MR. HIBBERT: This is near and dear to my own heart
3 as well I guess because my office has spent a fair amount of
4 time working on some of these changes and because the current
5 status quo is what we're in charge now of administering.

6 That status quo, among other things, is a rather
7 substantial volume of paperwork, in the neighborhood of
8 110,000 or so requests for label approval per year.

9 I realize I've got an audience here with differing
10 levels of familiarity with this issue so those of you who are
11 real familiar with it, bear with me on a couple of basic notions.

12 The concept of prior label approval is somewhat
13 unique to the Department because F.D.A. does not do it. One
14 of the requests, suggestions, criticisms we've heard over the
15 years, particularly in the last couple of years, is why not
16 get rid of it? Why look at all these labels?

17 There are some legal and practical problems with
18 this blanket approach. The statutes we work under do
19 talk in terms of labels being approved by the Secretary. This
20 proposal wrestles with how that can and can't be done,
21 but that is in the statutes.

22 In addition, there is the practical problem of the
23 fact that if you're a Federally inspected establishment, you
24 do have inspector there. You do have that inspection presence.
25 His job, among other things, is to see that products are

1 properly labeled.

2 In some respects that drives the issue into more
3 of a question of how centralized or decentralized we are and
4 how active or passive, if you will, of an approach we take to
5 labeling problems.

6 What has evolved over the year has been a fairly
7 active, fairly centralized approach where essentially every-
8 thing comes into Washington.

9 (The first slide was shown to the Committee.)

10 As you can see from some of the things that I've
11 highlighted, almost all labeling must be approved by the
12 Washington labeling office prior to the marketing of the product.
13 There are certain limited classes of labels that can be ap-
14 proved locally by the inspector himself. But generally it's
15 over 100,000 applications for label approval per year.

16 (The next slide was shown to the Committee.)

17 In addition to the label itself, we must be sup-
18 plied on the form with full ingredient and processing
19 information. I have a sample of the form later on, but
20 essentially you simply put your ingredients, percentage of use,
21 and your processing procedures on the form.

22 The label reviewer's job is to look at your label and
23 look at the product that you're describing and see if it is
24 appropriate in every respect to apply that particular label to
25 that particular product.

1 In addition, part of the label review function gets
2 into questions of making sure that the standards are being
3 followed and also that any restricted ingredients are being
4 used at appropriate levels.

5 There are mandatory features that must be displayed
6 on all product labels. I believe the next slide fleshes those
7 out a bit.

8 (The next slide was shown to the Committee.)

9 On any label that we review that's to be applied
10 to any meat and poultry product, you must have these basic
11 features: the name of the product, the inspection legend, the
12 ingredient statement, quantity of contents or net weight
13 statement, and the name and address of the manufacturer or
14 distributor.

15 In addition, if it is appropriate to that product,
16 you must have handling instructions.

17 (The next slide was shown to the Committee.)

18 This slide just fleshes out that same scheme of
19 things with a mock-up of the label. Again, the product name
20 on the top, it's a frankfurter, the mark of inspection, the
21 keep refrigerated statement, the ingredients, net weight and
22 packed for statement.

23 This is what we would characterize as a fairly
24 simple label.

25 (The next slide was shown to the Committee.)

1 The next slide takes that same product, and this is
2 the form that would come into our office accompanying it.

3 Again, this is a mock-up; this is no one's trade
4 secret or anything.

5 You'll see the specifications of the ingredients,
6 their percentages, and a good description of a routine hot-dog
7 processing procedure.

8 That will come in, be reviewed, presuming there are
9 no problems, be stamped up and sent back. At that point you
10 can use your label.

11 (The next slide was shown to the Committee.)

12 Just for comparative purposes, this next slide
13 works off that same skeleton and makes things a bit more com-
14 plicated. That becomes relevant later on when we're talking
15 about what kinds of changes we feel inspectors can work with
16 and what ones still ought to be centralized, and so on.

17 Here on this particular label you've got some
18 nutritional claims, negative claims, a nutritional label.
19 Down at the lower right you'll see -- it didn't show up real
20 well but that's an open dating piece of information; fresh-
21 ness beyond a certain date.

22 Just for comparative purposes, these are some of
23 the ways you can take one of our labels and get them a bit
24 more complicated by doing things like making nutritional
25 claims.

(The next slide was shown to the Committee.)

The proposal itself, which we published on May 21st and the comments are scheduled to end on August 19th, would really make some major changes in this system. These are mechanical changes, I should emphasize. We're really, through this vehicle, not saying anything new or different about what does and doesn't go on a label or what kinds of claims you can and cannot make. This is essentially an internal mechanics question of who looks at the label, who, if anyone approves it or doesn't approve it.

Under the proposal, the authority of the inspector in charge at a local establishment to approve labels and certain label changes would be greatly expanded within categories that we delineate later on.

In addition some limited categories of what we refer to as generically approved labeling would be established if the proposal's adopted. That is, categories of labels that you wouldn't need to pre-clear with the inspector either, that you would simply get a license through the regulation itself to use that particular label or make that change and simply provide the inspector with a copy, but there would be no need for any kind of a signing off by Departmental representative on the label before it's used.

24 The third item, and it's an important one, is
25 that participation in the program would be voluntary. Anyone

1 who would want to stick to the current system and get Washington
2 to look at any or all of his labels, regardless of what
3 category they come in, could do so. But in these categories
4 they would have the option of taking advantage of a generic
5 approval or getting an approval through the inspector.

6 Fourth is that the denial of an application by
7 the inspector will preclude the use of that particular label
8 unless and until some contrary authorization was to be obtained
9 from the central Washington office.

10 This gets into an area of concern as to how the
11 inspector is going to function in this environment, and the
12 notion here is that if he feels that the product would be mis-
13 branded based on his review of the label, that decision will
14 stick until Washington says differently.

15 Number five, is a somewhat different notion.
16 Under our current regulations, there's no discussion of nor
17 specific authority to issue what are called temporary ap-
18 provals. What has evolved within the system and what is still
19 current practice is to give such temporary approvals in
20 situations where there might be some minor deviation from the
21 regulations, some particular unforeseen hardship to a producer,
22 so on and so on, where we will allow the use of a label with
23 some minor deviations for a limited period of time.

24 That has evolved as a somewhat necessary kind of
25 fairness aspect of the present system, but sometimes it's

1 questioned as to what parameters we work under in that area.
2 So we have attempted to establish some
3 general guidelines and to put some time limits on the process.

4 What we would hope to achieve through this effort
5 is delineated in the next slide.

6 (The next slide was shown to the Committee.)

7 First of all, we'd like to be able to decrease the
8 turnaround time for approvals. That's somewhat self-evident
9 just in terms of mail time and the like. There are times
10 obviously when something develops in a hurry in a business
11 context and where it's going to be advantageous to people to
12 be able to get a new label put together and used in a couple of
13 hours as opposed to a couple weeks.

14 Next one, a reduction in paperwork, which again is
15 self-evident. Because it is voluntary as proposed, al-
16 though we have some experimental data because we did test this
17 notion in a pilot program, we are without hard numbers, but we do
18 feel that this could lead to a reduction of 50 to 75 percent
19 of the applications that come in to Washington by knocking
20 down that 100,000 plus to 50,000 or less.

21 Number three, a more efficient use of our
22 resources. Hopefully another advantage might very well be
23 having more time with our centralized experts to focus on what
24 might be more complicated or difficult problems. One dif-
25 ficulty we have with the present system is that the

1 individuals that review the labels are under a fair degree of
2 time pressure to keep the paper moving. A difficult problem
3 can arise in a stack of maybe 15 or 20 not so difficult labels
4 and perhaps not get the attention it deserves. This will,
5 through the sifting out process, help us to do better in
6 that regard.

7 Finally, a better communication between management
8 and the I.I.C. in this area. Because of the evolution of
9 central approval, in some instances people have suggested that
10 the inspector is inclined to be too passive in his relation-
11 ship with the plant in labeling questions because "Washington
12 says" and what have you. We are hoping for some improvement in
13 this area in enhancing the ability of the inspector to work
14 these problems with people on the spot.

15 In terms of categories themselves, again as I
16 indicated earlier, there are three basic categories.

17 (The next slide was shown to the Committee.)

18 Those which would continue to require central
19 Washington approval. Number two, those which would be ap-
20 proved by the I.I.C. In those instances copies would be sent
21 to us in Washington and will be subject to audit. And if
22 necessary, some kind of follow-up action would be taken if there's a mistake.

23 The scheme of the system is that the error rate
24 should not be that high for inspector approved labels because
25 there's been a deliberate sorting out of label problems that

1 might not be that complicated and might not require a great
2 deal of special expertise, but nevertheless we are going to
3 audit those decisions.

4 Number three, generically approved labeling
5 situations will be specified in a moment where even that
6 degree of paperwork is not deemed to be necessary.

7 As you can see from the asterick in the first two
8 instances, you will still need some form of written authori-
9 zation from the Department in order to use that label and in
10 the third instance you will not.

11 I'll just run over this list relatively quickly.

12 (The next slide was shown to the Committee.)

13 These are, under this proposal, modifications you
14 will be able to make to your label without any sort of paper-
15 work. You simply have to provide the inspector with the
16 modified label you're going to use.

17 As you can see from the asterisks, some of these
18 are specified in the current regulations. This is an
19 expansion of a existing category, but the category in the past
20 has been relatively narrow and hasn't been used that much.

21 The large ones are reductions of labels, substi-
22 tutions of words for abbreviations or visa versa, spelling
23 out pounds versus "lbs," something like that. Filling in
24 certain blanks on master or stock labels that have already
25 been approved; putting holiday kinds of designs on the labels,

1 around Christmas time putting a wreath on there, or something;
2 certain changes in direction such as how to open a container
3 or how to store a product; coupon, cents off statements;
4 cooking instructions; Uniform Product Code; those kinds of
5 things; changes in the signature line; the name and address of
6 the packer and distributor; net weight changes; recipe sug-
7 gestions; punctuation changes; and changes in the establishment
8 number.

9 In all of those instances the labels would be
10 generically approved, and that is probably a bigger area than
11 you would think of. It's worth keeping in mind when you talk of
12 approving new labels, in most instances what you're really talk-
13 ing about are these kinds of changes. Maybe not these kinds,
14 but relatively minor changes in something you're doing already
15 and simply modifying an ingredient or a promotion thing or what
16 have you.

17 Mr. McDade.

18 MR. MCDADE: Could I ask on number three, if that
19 were expanded or not expanded, if that were leaving out blanks
20 in there. Now, is the blank only for the name of the
21 distributor, or would that be a blank that might leave out the
22 class or part?

23 MR. HIBBERT: I think we covered that in some of
24 the inspector changes, that gets broader. But in this
25 category that is simply having something approved in blank
without the distributor's name.

1 DR. MC DADE: That's just the distributor?

2 MR. HIBBERT: That's right.

3 DR. MC DADE: The other's important; you will come
4 to it?

5 MR. HIBBERT: Yes.

6 These are types of labels which the inspector could
7 approve. Now again this is a situation where you've got to
8 fill out your form, you've got to hand it to the inspector,
9 he's got to look at it, sign it, and give it back to you, as
10 opposed to the generic category that I've just delineated.

11 (The next slide was shown to the Committee.)

12 The first one is an important category. It's final
13 labeling, having sketch approval which is prepared without
14 modification from that sketch, or with certain minor modifi-
15 cations that fall into one of these other categories.

16 Under our current system we give what are called
17 sketch approvals of labels. What that entails is simply
18 giving a dry-run, if you will, on a label submitted with the
19 form, but not the actual label to be used. This is really a
20 service that we provide. We still, under the present system
21 require a follow-up review of the label itself, but frequently
22 people with take advantage of that because they'll want to
23 clear up any problems that might arise in the label product
24 prior to the actual printing of the plates and of the labels
25 themselves.

1 There are many situations where we have issued a
2 sketch approval and where either there are no modifications or
3 the modifications are minor. In that kind of a situation,
4 after you get them approved, you can simply show it to the
5 inspector and have him approve it.

6 Number two, labeling for single ingredient pro-
7 ducts which do not contain quality claims. A label for some-
8 thing like a chicken leg or ground beef, or what have you,
9 where there are no other ingredients. The ingredient really
10 is the product. The label is not otherwise filled up with all
11 sorts of other different kinds of claims.

12 Number three, is where a label which has been
13 approved and with just minor modifications, which we've already
14 started to get into.

15 Number four, products served to the Federal
16 government in contract, shipping containers, non-union food
17 products, inspection legends, parens, and various inserts,
18 tags, liners, and other such devices.

19 You can see from the asterisk again that some of
20 this reflects as guesting authority in the current regulations,
21 and again the category is being expanded.

22 In all of these situations you have the option of
23 getting the inspector to approve such a label or labeling
24 change versus having to send it to Washington.

25 (The next slide was shown to the Committee.)

1 Now the next is a further definition of what are
2 these minor modifications that are addressed in terms of what
3 the I.C.C. can approve, a minor modification contemplating the
4 fact that there's a preexisting label in the first place.
5 Name changes, deleting the word "new." That little thing
6 itself generates a fair amount of paperwork because a lot of
7 people will put new on a label and put it in a new marketing
8 area. Under the present system, everytime you put it on or
9 take it off, you've got to send it to Washington because it's
10 a new label.

11 Addition, deletion, or amendment of handling
12 instructions, changes in ingredient quantity without a change
13 in the order of predominance. That is essentially
14 a formulation change off the same approved label because one
15 of our basic requirements is to list the ingredients in their
16 order of predominance, but what we also have is a piece of
17 paper on file with the specific formulation. This will give
18 greater leeway to change that formulation without changing
19 that predominance without extra paperwork.

20 Addition, deletion, or substitution of the grade
21 shield.

22 (The next slide was shown to the Committee.)

23 This gets into the topic I discussed earlier of
24 temporary approvals.

25 As I indicated, we did feel it was worthwhile to

1 get that addressed in the regulations.

2 As you can see, we attempted to just lay out some
3 general criteria which we feel are valid in the area.

4 Essentially we are saying that we will consider
5 requests for granting temporary approvals when these criteria
6 are met. When the labeling does not misrepresent the product,
7 present any potential health, safety or dietary problems, and
8 would not set up an unfair competitive situation, and where
9 the denial of the request might create some undue economic
10 hardship.

11 As we proposed it, we did propose a flat 180 day
12 limit on the life of a temporary approval. Most of the time
13 they're shorter under the current scheme of things, but on
14 rare occasion in the past they have gone on longer and it
15 becomes a management and mechanics kind of headache to make
16 sure that the system is cleaning itself out of those things.

17 As I indicated today, the comment period is still run-
18 ning. We have at this point received about 15 or 20 comments,
19 which are essentially supportive. There have been some
20 reservations about questions like making sure we do have proper
21 training, that we not be overly restrictive as to what we'll
22 look at in terms of sketches, there is some concern about the
23 limits on the temporary approvals.

24 There is more to this than the exercise of the rule
25 itself. We have had to do a fair amount of planning in areas like

1 training and have projects ongoing, working with the inspection
2 people to make sure that if we're going to go ahead and do
3 this, that the thing is properly organized and lined out and
4 everyone's trained properly. So that will absorb a fair amount
5 of our energies in the next several months.

6 DR. ALFIN-SLATER: Is this just one person who is
7 going to make these decisions, or will there be a committee?

8 MR. HIBBERT: Which types of decisions? What do
9 you mean?

10 DR. ALFIN-SLATER: The ones, for example, that you
11 had on the slide just before.

12 MR. HIBBERT: For temporary approvals?

13 DR. ALFIN-SLATER: One in particular that bothered
14 me was that denial will create a financial hardship. Still,
15 I think that the person presenting the label has to prove that
16 all the other criteria apply, safety, no health hazard, etc.

17 I'm just wondering, who makes the decision as to
18 whether deny or approve a label? Is it one person or a
19 committee? Under these new guidelines.

20 MR. HIBBERT: First of all, I think it is our
21 intention that these are cumulative criteria. The simple
22 hardship is not enough. The simple hardship obviously does not
23 outweigh a safety concern.

24 In terms of who makes the decision, they are made
25 by individuals. The way we work, in terms of bodies, there are

1 eight line label reviewers. They have an immediate supervisor
2 in a branch, and then I am the Director of the office which
3 includes that branch.

4 We know that the reviewers themselves will not
5 give temporaries; their supervisor will, and then up the line,
6 myself, my Deputy or other people in the Agency will also give
7 them. But they are generally given by individuals.

8 DR. BRICKENKAMP: I have a question. How many in-
9 spectors in charge are there in the field?

10 DR. HOUSTON: There are 7,000 Federally inspected
11 meat and poultry plants, and many of those are under patrol
12 inspection, most of the smaller plants. So as a result you'll
13 have one inspector in charge covering several plants. At the
14 last count, I think there probably are around 2,500 to maybe
15 3,000 inspectors in charge.

16 DR. BRICKENKAMP: Thank you. The reason I'm asking
17 is, this sounds very useful for the industry, but I wonder how
18 much it's going to cost you all because of training and such
19 things as that.

20 You have eight people now looking at the labels.
21 How big a program and for how long have you planned in order
22 to meet the needs of the training and so on?

23 DR. HOUSTON: What we did before we ever published
24 this proposal was to carry out a pilot program utilizing these
25 principles.

1 DR. BRICKENKAMP: I read the Federal Register
2 about the manual and self-training and so on. Do you intend to
3 continue that?

4 DR. HOUSTON: Yes, we do. But I think the main
5 point is that this system has been pilot tested. It is not
6 something that is a gleam in our eye. It's something that has
7 been carried out at the field level. From our experience there,
8 we are quite confident that it will work.

9 We recognize, as you point out, it will take a
10 great deal of training. The extent that the industry will want
11 to participate is up to them, it is voluntary.

12 The major problem, of course, is training, and to
13 be sure that the inspectors apply those criteria in a uniform
14 manner. As you imply, when you go from eight people to several
15 thousand, uniformity can become a problem. However, we are
16 limiting what those inspectors do to some rather simple
17 changes.

18 During our pilot program we found out that the
19 error rate was not that high, and the errors that were made
20 were of an insignificant nature.

21 I think we have a lot of data which will show that
22 this can be done in a practical way considering the inspection
23 system that we have to carry out.

24 DR. BRICKENKAMP: I wasn't asking the question
25 from an adversarial point of view.

1 I was really trying to find out approximately how
2 much it will cost the Department in the training and the extra
3 things because the Federal Register article did say that a
4 10 percent error rate had been seen to exist and that you
5 intended to go a little bit more extensively into training.

6 Knowing that there are 2,500, at least, people out
7 there who will need the training, I assume this is going to
8 cost the Department a certain finite amount in terms of money
9 and resources.

10 DR. HOUSTON: Yes, but it will not be out of pocket
11 money. It'll be absorbed within the current budget by re-
12 directing some training efforts to other areas.

13 I can't tell you exactly what that's going to be,
14 but we will not be asking for additional monies.

15 MR. HIBBERT: Not all the aspects of the training
16 have been fleshed out, but we're going to be relying pretty
17 heavily on things like self-instruction guides.

18 Keep in mind also that you're not starting at
19 square one. You're talking about questions that arise that he
20 or she is generally familiar with to begin with just being in
21 the plant, and by selection the categories should not impose
22 a lot of real difficult problems.

23 DR. HOUSTON: Are there any other questions?

24 MRS. CRAMER: Just a comment. 22106 page indicated
25 the comments that had been made were primarily negative. Would

1 you care to comment on whether this was an organized effort,
2 and why these comments, do you feel, came in?

3 MR. HIBBERT: Are you talking about comments to an
4 earlier proposal?

5 MRS. CRAMER: On the February, 1980, proposal that
6 was indicated here.

7 MR. HIBBERT: In February, 1980, we really were
8 proposing something quite a bit different. We were talking
9 about a continuation of centralized approval but we were pro-
10 posing some changes in the manner in which we reviewed them.

11 Under the current system approximately half of the
12 labels come in to us through the mail and half of them come in
13 in person by representatives of companies, either employees or
14 centralized Washington services that provide that service to
15 the industry. That has been an item of some controversy over
16 the years. There was some sentiment at that time that it was
17 somewhat unfair to be giving appointments to people walking in
18 on day one while mailing labels were sitting for perhaps a
19 couple of days because of resources.

20 As the discussion indicates, there were negative
21 comments. There was some organized letter writing against
22 that proposal.

23 But that is quite a bit different from what we're
24 proposing now.

25 MR. LOUNSBERRY: I have a question.

1 You mentioned, and maybe I didn't hear you correctly,
2 but I thought you said there were relatively few comments
3 in so far and that most of them were positive; is that
4 right?

5 MR. HIBBERT: That is correct.

6 MR. LOUNSBERRY: Fifteen or so.

7 MR. HIBBERT: There may very well be more between
8 the time I came here. They tend to come in towards the end.

9 DR. ROSS: Did you ever implement the G.A.O. suggestion,
10 first in, first out, on the labeling?

11 MR. HIBBERT: That really relates back to that
12 question about the 1980 proposal. That proposal was not
13 adopted.

14 As a practical matter we haven't had that much of
15 a problem because the staffing is somewhat better than it was
16 back then. We really do not have much of a backlog problem.
17 We're generally getting to yesterday's mail today. As long as
18 we can do that, we don't have a big problem in the backlog area.

19 DR. ROSS: Another question. In view of the apparent
20 vehemence of Herson's letter, would you care to comment?

21 DR. HOUSTON: For purposes of clarification for
22 the rest of the Committee, there is a label expediting firm in
23 Washington that has written to a number of packers and to
24 Congress which reflects adversely on this proposal.

25 I think you can see that if this proposal were to

1 be enacted, it would cut down on the amount of business the
2 label expeditors conduct at the Washington level.

3 As Bob mentioned, if we go from 100,000 labels to
4 50,000 labels, it's conceivable that a 50 percent reduction of
5 that service could occur.

6 I will not comment on the Herson allegations nor the
7 Herson letter. It was very critical of the Department. I
8 will not comment on it because we are in rule making, and I
9 don't want to pre-judge the issue.

10 I would say though, that I think the meat and poul-
11 try industry, the people in the industry, have the intelligence
12 to make their own decisions and will come to a carefully con-
13 structed decision when they decide to comment on this without
14 having to rely on the kinds of information they got from
15 that particular document.

16 I would add also that Mr. Hurson has made al-
17 legations of corruption and bribery against a number of
18 individuals over the last 15 years, individuals within the
19 Department of Agriculture, and he may even have included me.
20 The number is so long and lengthy that I forget who's on it.

21 Those allegations have been investigated on a
22 number of occasions by the Inspector General. There have been
23 F.B.I. investigations. And at no time, and I emphasize, at no
24 time, have those allegations been corroborated by
25 independent investigations by the groups I mentioned.

1 Of course it is disappointing that Mr. Hurson con-
2 tinues to make those allegations. Obviously, as a citizen
3 a taxpayer, he has a right to do that.

4 We'll also carefully consider Mr. Hurson's com-
5 ments when we construct the final rule.

6 DR. ALFIN-SLATER: This is actually what I had in
7 mind when I asked whether this was going to be one individual
8 or a committee.

9 I think if you have more than one individual, you
10 can sort of bypass this kind of criticism. You can't corrupt
11 a whole committee.

12 DR. HOUSTON: Dr. Foster, did you have a comment?

13 DR. FOSTER: Yes, and that's what it is, a comment
14 and not a question.

15 I don't have pipelines to all the meat industry,
16 obviously, but I hear something now and then. The question of
17 uniformity, the need for uniformity and the need for better
18 trained inspectors always comes through.

19 I mention this only because I think it deserves a
20 great deal of emphasis.

21 One person mentioned the hassle they'd had with
22 their inspector because they wanted to change the color of the
23 label and he wouldn't let them, so they went to Washington and
24 it was approved.

25 I don't know how you can avoid that. Obviously it

1 becomes a matter of individual judgment.

2 The training and guidance to these people so that
3 they have something common to follow is going to be absolutely
4 essential if this is going to work. I recognize the fact that
5 anyone who doesn't like the system can always go to Washington.
6 That's their alternative.

7 Perhaps that will be the best way, or a way out of
8 their problem, if they have one. But obviously you're trying
9 to get away from that. You're trying to get them to settle
10 these things locally. The best you can do in training these
11 people to understand what is acceptable and what isn't will
12 make it go a lot smoother.

13 DR. HOUSTON: Well, I don't want to start a
14 discussion that would negate the kind of discussion we want
15 tomorrow in the area of substance, but I would make several
16 notes.

17 First of all, we're proposing to slaughter a sacred
18 cow. You know the problems that occur when you do that. We're
19 changing a system that's been in place for many years,
20 and many people have come to depend upon it, including the
21 label expeditors, who have evidently developed some good
22 businesses. I'm not privy to their financial statements, but
23 I suppose they're making money, they're still in business.

24 It doesn't mean we have to continue those systems
25 if they can't be improved. If we can cut out red tape and if

1 we can do it better, more efficiently, we should, without
2 losing effectiveness.

3 I would make one other comment to add to Bob's
4 presentation, and that is the fact that we did get a number a
5 petitions in this area. Notably, the National Food Processors
6 Association, the National Margarine Association, and the
7 American Meat Institute. The National Food Processors As-
8 sociation did ask us to go all the way, to do away completely
9 with prior approval of labeling. The Amrcian Meat Institute
10 petition did not go that far.

11 I think that reflects feeling among many meat
12 packers that they do not want to see this system done away with
13 at least at this point. They have come to use that system, to
14 see the system as a protection to them, especially small
15 plants. They see the review of labels as a way that some
16 companies cannot gain an economic advantage by producing a
17 product that might be of lower quality or not meet USDA
18 standards. By having the U.S.D.A. overseeing that system, it
19 provides greater uniformity in the industry in terms of
20 competition and everyone having to operate from the same
21 ground rules.

22 The last point I'll make is that F.D.A. does no
23 prior approval of labeling. Companies are free to develop
24 their own labels. Of course, there's risk involved. If
25 they're not in compliance, they're subject to being taken off

1 the market, they're subject to recalls and they're subject to
2 litigation.

3 That is another reason that there are members in
4 the meat industry who would still want the opportunity to have
5 labels prior approved or pre-approved; to avoid possible recalls,
6 to avoid the possibilities of litigations, and so forth.

7 MR. CARBAUGH: Mr. Chairman. The voluntary aspect
8 of this program, if I were a meat packer and I did not wish to
9 have the inspector in charge approve my label, I could request
10 that Washington approve it; is that the way that works?

11 MR. HIBBERT: That's correct.

12 MR. CARBAUGH: The other thing I'd like to ask, are
13 there any implications at all in terms of the system as it
14 relates to international trade?

15 MR. HIBBERT: No, I don't think so. You still need
16 to export, an approved label.

17 MR. CARBAUGH: It wouldn't make any difference
18 where that approval occurred?

19 DR. HOUSTON: You're talking about a product coming
20 into the United States or leaving?

21 MR. CARBAUGH: Leaving.

22 DR. HOUSTON: These same rules would apply.

23 You've raised a point, though, and I think we need
24 to mention it so if there are any comments tomorrow they should
25 be made.

1 We also give approval or pre-approval to labels of
2 imported products, products that will enter the United States.
3 For example, if a packer in Canada wanted to ship a product
4 down here, they must get that label pre-approved. If someone
5 wants to send in a ham from Denmark or a canned ham from
6 Poland, those labels are pre-approved, also.

7 I don't believe our proposal would change that
8 procedure.

9 MR. HIBBERT: No, it wouldn't, because as a
10 practical matter you don't have the inspector over there.

11 DR. HOUSTON: There's an inspector over there but
12 not our inspector.

13 DR. BRICKENKAMP: I have a question about general
14 keeping of catalogues of such. I assume everything that the
15 inspector in charge will approve will have to go to Washington
16 so that somebody keeps track of what's going on.

17 MR. HIBBERT: We're going to get a copy of every
18 inspector approved label and it will go into a central file
19 and it will be there for data purposes and also for auditing
20 purposes.

21 DR. BRICKENKAMP: And also training purposes?

22 MR. HIBBERT: Yes.

23 DR. BURNETTE: In the proposal it mentions that
24 there's a numbering system that's been invented in which all
25 of these labels will still go in the same relatively

1 chronological numbering system even though they're approved out
2 in the plants.

3 Can you tell me how you managed that mathemati-
4 cally?

5 MR. HIBBERT: No. I can tell you that we're
6 working on it and that there are people far better with numbers
7 than I that I'm sure will come up with something intelligent,
8 but as of now we don't have it all fleshed out.

9 DR. HOUSTON: Any other questions for clarifi-
10 cation on that area?

11 MR. LOUNSBERRY: You said something about 7,000
12 Federal inspectors in charge?

13 DR. HOUSTON: There are about 7,100 plants that
14 are under Federal meat and poultry inspection.

15 MR. LOUNSBERRY: Well, I assume there's a Federal
16 inspector in charge, the head honcho where they have 47, 48 in
17 one plant, who would be authorized to make a label change, would
18 it be the inspector in charge, then?

19 DR. HOUSTON: That's right. Each plant has des-
20 ignated for that plant an inspector in charge.

21 MR. LOUNSBERRY: So you would have, conceivably,
22 about 7,000 different, potential individuals making judgments?

23 DR. HOUSTON: No, sir. The reason is that many
24 small plants are covered under what we call a patrol assignment;
25 when we may have four or five or six plants assigned to one

1 inspector. In fact, the majority of plants are under patrol
2 inspection so as a result I would guess that we have 2,800 to
3 3,000 inspectors in charge.

4 MR. LOUNSBERRY: That must be in those states that
5 no longer have Federal and state inspection.

6 DR. HOUSTON: You're correct because --

7 MR. LOUNSBERRY: -- because you sure as the devil
8 don't have any patrol inspectors, Federal inspectors other than
9 a few, about six, for the whole state of Iowa in 440 plants.

10 DR. HOUSTON: Where we have had to designate state
11 inspection programs you're quite correct, because generally
12 those are small plants requiring less than a full inspector in
13 that plant. We have designated 23 states. Everytime that des-
14 ignation occurs, many, many more small plants have to be
15 regulated by the Department of Agriculture.

16 MR. LOUNSBERRY: Then in a ballpark figure, what
17 would you guesstimate or estimate the number of inspectors in
18 charge that would conceivably have authority for approving a
19 label, if this rule goes through?

20 DR. BURNETTE: I have the number. As of May the
21 proposal says 3,200.

22 DR. HOUSTON: The answer is 3,200.

23 MR. LOUNSBERRY: Was that in here? I missed it if
24 it was?

25 I was just going to make another observation on the

1 first one. You were talking about it was a matter of house-
2 keeping, on the Margarine Standard. I think every other page
3 is all we had there, so you couldn't have any continuity about
4 what the rule was, what we received, anyway.

5 But it doesn't make any difference. Somebody said,
6 "Who cares," only the margarine people.

7 MR. HIBBERT: I believe that was a mechanical
8 error as opposed to any kind of manifestation of our attitude.

9 MR. LOUNSBERRY: Cut down on the observations,
10 anyway.

11 DR. WHELAN: I just had a question about the extent
12 of the problem that we're dealing with here, the prior labeling.
13 How many violations are there under the old system? Are they
14 expected to increase? Is this a big problem? Are people
15 making false claims?

16 MR. HIBBERT: The way our system works you don't
17 really wind up with violations, you wind up with labels that we
18 won't approve.

19 DR. WHELAN: Well, is that an extensive number?

20 MR. HIBBERT: Yes. I couldn't give you a hard
21 number. When you get into more complicated areas, when you
22 get into areas like nutritional claims and things of that
23 nature, you get areas of interpretation as to when a label is
24 and is not misleading. That arises fairly frequently.

25 DR. HOUSTON: Keep in mind that if we go with this

1 proposal, the kinds of labels that would be approved by the
2 inspector in charge at the plant level, even if he made an
3 error, would probably not be an error of significance, nor
4 an error that could create a public health problem or a
5 serious problem, as opposed to those where we might have more
6 complex claims, which would still be approved by the central
7 staff.

8 MR. HIBBERT: The kinds of things that we go back
9 and forth with, have arguments about with people, will still
10 probably come in to Washington and there will still be some
11 back and forth.

12 DR. ROSS: Will these inspecting chaps still have
13 an opportunity to consult with Washington on questionable
14 labels?

15 MR. HIBBERT: Yes, that's part of the planning
16 process we're doing. We're probably going to do something in
17 the nature of having reviewers be designated as contacts within
18 a given geographical area, things like that.

19 MS. MUCKLOW: For people who have been involved in
20 processing labels, this would mean that, for instance, if they
21 have a sketch approval and then they send the label in for
22 final, they will cut in half the number of labels that have to
23 go to Washington simply because if they got a sketch approved,
24 the final can be approved by the meat inspector.

25 Irregardless of any part of this proposal, that

1 would cut the very substantial quantity of labels. It's
2 extremely important to people who are farther away from
3 Washington in terms of saving time. It's very irritating to
4 get your supply in from the printer and you can't do anything
5 with it because it's got to go to Washington. It's going to
6 probably take one to two weeks with today's mail service, even
7 when Washington gives it a pretty quick turnaround.

8 You're simply reducing the volume of paperwork
9 that really is rather unnecessary anyway.

10 DR. HOUSTON: Any other points? Mr. Lounsberry.

11 MR. LOUNSBERRY: Another thing, the time involved
12 in about 70 percent if it follows the pattern of the pilot
13 project, would be greatly reduced, too, as I read it anyway.
14 About 65 to 75 percent of the labels were approved in about an
15 hour's time of the inspector in charge, compared to all the
16 other time involved.

17 DR. HOUSTON: Any other points on that matter?

18 SODIUM LABELING

19 When we were together last year the Committee was
20 given a briefing on the Administration's initiatives to reduce
21 the dietary intake of sodium. In a very general way we out-
22 lined some of the steps that would be taken by F.D.A. and by
23 U.S.D.A., and how we would be working together.

24 Today we want to give you somewhat of a progress
25 report on what's occurred since then. Tomorrow you'll have an

1 opportunity to give us your counsel on this very important
2 public health area.

3 MR. HIBBERT: Unlike the other two, this is really
4 a more generalized kind of update. It doesn't translate into
5 a specific proposal of one particular concrete thing.

6 (The first slide was shown to the Committee.)

7 The first slide is really an attempt to link back
8 to the discussion that Dr. Nelson made at the last meeting.
9 These are some of the general topics covered last time. There
10 was some specification of the reason for concern about sodium
11 levels in the diet, and there was some discussion of the
12 Department's policy base as evidenced by things such as Mr.
13 McMillan's testimony.

14 The Department, in addition to and in conjunction
15 with the Food and Drug Administration, is working on encourag-
16 ing a voluntary approach to sodium labeling, and the develop-
17 ment of new low and reduced sodium foods.

18 This was also going to entail a commitment to
19 research efforts and a public information effort as well.

20 (The next slide was shown to the Committee.)

21 In terms of public information, there is a new
22 joint H.H.S./U.S.D.A. sodium publication called SODIUM, THINK
23 ABOUT IT. I do have one copy with me if anyone wants to look
24 at it and I'm sure we can arrange to provide copies.

25 Oh, you have them already.

1 In addition we have the label approval record it-
2 self which gives us some gauge on what's happening and who's
3 doing it. We've gotten a steady increase in the level where
4 we now have approximately 55 companies with in excess of 2,000
5 approved labels.

6 Now those numbers are a little tricky because keep
7 in mind that those are numbers of labels and that that is not
8 proportionate to the volume of product. What we have is
9 approvals. A number of some of the major companies have gone
10 with sodium labeling and are out on the market place. They
11 are people like Oscar Mayer, Banquet Foods, Campbell Soup, a
12 number of the baby food manufacturers such as Gerber. That
13 really reflects relatively high volume of actual product on the
14 market place with sodium labeling.

15 Within our focus, of course, that's meat and
16 poultry products.

17 We also engage, not in my own office but in the
18 science element of the Agency, in a sodium monitoring program.

19 (The next slide was shown to the Committee.)

20 This is an attempt to develop additional baseline
21 data on sodium levels in a variety of foods. There are I
22 believe nine target products that are being studied and samples
23 are going to be coming in throughout the year, which will generate
24 an internal data base, if you will, for a sodium level in a
25 variety of the products we inspect.

1 I mentioned research and other kinds of public
2 information. There is a research effort that entails an agree-
3 ment with the Agricultural Research Service and has four basic
4 aspects: applied research in reduction in food, the evaluation
5 of possible substitutes, the monitoring itself, and the role
6 of sodium in food safety and preservation.

7 (The next slide was shown to the Committee.)

8 In the public information area, in addition to the
9 pamphlet, there are things being worked on such as, I believe,
10 two television spots which should be airing in the next few
11 months. Also a number of radio spots, including some that are
12 geared to specific targets in the population such as Black and
13 Hispanic audiences.

14 The last item on here is of some significance,
15 concrete significance within the meat and poultry world, that
16 is, changes in our sodium verification policy. An area of
17 some controversy and some analysis in our system flowed and
18 flows from the earlier requirement that we impose quality con-
19 trol monitoring requirements on anyone who is making a sodium
20 declaration on a label. We received a fair amount of concern
21 and complaint about the expense associated with that, and we're
22 told that in effect that this was inhibiting the resort to sodium
23 labeling because the backup laboratory work was too expensive
24 and time consuming.

25 That bulletin relaxed some of those requirements to

1 the extent that it has shown a greater willingness on the part of
2 the Department to dispense with quality control requirements in
3 situations where there was significant, generally accepted data
4 such as Handbook 8 data, which would support the sodium values
5 being claimed, or if there was a more specific data base within
6 an organization or a company which would support those claims.

7 In those situations we have pulled back on some of
8 our backup quality control requirements.

9 (The next slide was shown to the Committee.)

10 This is an attempt to just sort of sketch out for
11 you our current policy on sodium labeling itself. I should
12 emphasize that we are in something of a transition situation as
13 you might imagine, in particular since we do have an F.D.A.
14 proposal pending now, which I'll get to in a moment.

15 But as of now sodium content information must be
16 presented in milligrams per serving. This is voluntary, again,
17 I should emphasize.

18 If you make such a declaration, you are not
19 required to also use nutritional labeling. That is again your
20 option, but your choice of putting sodium information on the
21 label does not dictate that you put a full nutrition label on
22 your product.

23 Conversely, if you have a nutrition label, you are
24 not required to include sodium information within it.

25 In terms of claims, we will approve claims with

1 adequate supporting data for things such as no salt added, and
2 we will approve a low sodium claim on the basis of 35 milli-
3 grams per 100 grams. This is an area of some controversy.
4 I'll get into that again when I get into the F.D.A. proposal
5 because F.D.A. is going in a different direction.

6 We will allow some comparative claims if they are
7 adequately explained.

8 In terms of support data and this is worth keeping
9 in mind, that again we still have prior label approval and we
10 do have a situation where we, unlike F.D.A., are
11 evaluating data in support of that in the first
12 instance before the label is used.

13 As part and parcel of label approval in this area,
14 we will require some degree of analytical data to support the
15 values being claimed on the label. That is distinct from the
16 backup quality control effort that I talked about earlier.
17 That is an initial data presentation situation. The quality
18 control program I've already mentioned.

19 (The next slide was shown to the Committee.)

20 We issued what's called a policy memo approximately
21 two months ago which made some changes in this area, particu-
22 larly in the low sodium claim area and in a few other situations
23 and that sparked some controversy. That was issued at about
24 the time the F.D.A. proposal was issued. It was an attempt in
25 some respects to reconcile some of the differences with F.D.A.

1 that I'll get into in a minute. There was also some concern
2 that that was premature, that we had not allowed sufficient
3 debate, initial debate on the issue as would be driven in
4 particular by the F.D.A. document.

5 As a result we've pulled back on that. That memo
6 is no longer in effect. As I mentioned the old low sodium
7 policy is still effect, and we are now working on reconciling
8 these guidelines.

9 DR. HOUSTON: Before we go on, I was curious to
10 note, as Bob pointed out, at this point in order to encourage
11 sodium declarations, we are not mandating full nutrition
12 labeling as a requirement. At the same time we're not
13 requiring sodium as part of nutrition labeling; again
14 because we want to keep as much nutrition information on that
15 label as possible. If someone doesn't want to make a sodium
16 declaration, then they're going to drop their whole
17 nutrition label.

18 We're trying to be as flexible as we can and still
19 get as much nutrition information on that label. I don't want to
20 continue to take up Mr. Jacobsen's press release here, but one
21 of the reasons that he's called for the resignation of John
22 Block is because he's refused to require sodium declaration as
23 part of nutrition labeling.

24 I can assure you that Mr. Block is not involved in
25 the day-to-day decisions with regard to sodium declarations

1 and nutrition labeling. I guess if somebody needs to
2 resign, it's going to have to be Bob or me because we
3 made that decision.

4 DR. ALFIN-SLATER: Let me state something here. It
5 seems to me that you are absolutely convinced that sodium
6 contributes to hypertension in humans when this has never been
7 proved. It's been shown in animals, but the final word on
8 sodium as far as human high blood pressure and hypertension
9 are concerned is not in.

10 It maybe that it's a potassium deficiency, or a
11 calcium deficiency, or a magnesium deficiency.

12 I'm just wondering, I know that you have a human
13 nutrition division in Beltsville, is any work being done on
14 sodium and its relationship to hypertension in humans?

15 DR. HOUSTON: Any working being done in
16 that area is probably going to be done at the Heart, Lung and
17 Blood Institute, or by H.H.S.

18 In going into this program early in this Adminis-
19 tration, there was a general agreement by F.D.A. and U.S.D.A.
20 or H.H.S., Assistant Secretary Brandt and Commissioner Hayes,
21 that this was a needed and necessary program in their view,
22 and especially Dr. Brandt as the Chief Health Officer, so to
23 speak, for the Federal government. In his view it was the
24 kind of information that the public needed.

25 I think that some controversy still exists. I'm sure

1 that they would state that there's a strong correlation between
2 sodium intake, or at least reduction in sodium and improvement
3 in patients being treated for hypertension.

4 From that standpoint and some of the clinical
5 experience that Dr. Hayes had during his years in Pennsylvania,
6 that decision was made. I think at least from their standpoint
7 there's enough evidence that people ought to be aware of what
8 they feel is a strong correlation, and that we ought to provide
9 information on the amount of sodium in the foods we eat.

10 Again, though, I would emphasize that we are not
11 mandating sodium declarations. We are not mandating sodium
12 claims. What we're doing is setting up a system so that
13 people who want to voluntarily make sodium declarations or
14 make sodium claims can do so and that we can attest to their
15 truthfulness.

16 Dr. Whelan.

17 DR. WHELAN: I think we have to make a distinction
18 between the consensus in the scientific community on people
19 with hypertension being adversely affected by salt, by sodium,
20 and those in the general population being so affected.

21 In this little booklet I was a little troubled
22 because it seems to say to the consumer we take in more sodium
23 than we physiologically need and then, therefore, ergo, it is
24 harmful and we'd be better off without it.

25 I think that is skipping a very important part of

1 the scientific dialogue which is still in process. By talking
2 about the labeling, voluntary or not, and putting it out for
3 the entire population, I think it suggests that a consensus
4 has been reached on sodium as being a causative factor in
5 hypertension where I don't believe it has.

6 DR. HOUSTON: We welcome those comments and
7 tomorrow when we get into the discussion on the substance of
8 these programs, we certainly want to hear more in that area
9 and take it into account as we move with this program.

10 DR. CRAIG: Didn't we have a report at the last
11 meeting about 20 percent of the population would respond to
12 a reduced sodium level in the diet? It seems like there was
13 some figure that came forth at that meeting.

14 DR. HOUSTON: I don't recall.

15 DR. ALFIN-SLATER: I think that's right. I've
16 seen that figure, too. But this means that 80 percent of the
17 population is not affected.

18 DR. CRAIG: It also means that 20 percent might
19 want to make the choice. That's what I'm reading into this,
20 now.

21 MR. HIBBERT: The F.D.A. proposal which I'll get
22 into in a moment cites an estimated figure of 60 million in
23 the United States.

24 DR. BURNETTE: While you're looking for that, I'm
25 just going to say for the record that I used that figure last

1 time and it's because the F.D.A. is using the high number of
2 up to 25 percent, and the GRAS survey used a low number of
3 down to 15 percent. So somewhere around one out of five, one
4 out of four people are responsive to sodium. That's how it
5 got into the record last time.

6 MR. HIBBERT: The F.D.A. proposal which I mentioned
7 was issued on June 18th and there are some differences from
8 what they're proposing and our present policy.

9 In the first instance they're also requiring a
10 declaration of milligrams per serving. They're taking a view
11 that a sodium declaration will mandate nutrition labeling,
12 but they are taking the view that this will become, if this
13 part of their proposal's adopted, a required feature of a
14 nutrition label. In other words, you will be able, if their
15 proposal's finalized, to make a sodium statement without a
16 nutrition label. But if you have a nutrition label, it will
17 have to have a sodium statement in there.

18 That is different from what we're doing now.

19 In terms of claims, they did some additional
20 elaboration of claims and, if you look at the second item, you
21 see that point of controversy. They proposed a low sodium
22 claim to run with 35 milligrams per serving as opposed to a
23 set value such as 100 grams.

24 They also further defined claims such as "moderately
25 low sodium," "reduced sodium," and some discussion of comparative

1 claims and items such as sodium free and salt free.

2 In terms of supporting data, again keep in mind
3 that mechanically their's is quite a bit different than ours.
4 They talk in terms of compliance criteria in terms of a 20
5 percent margin for error. As is relevant to what we were
6 saying earlier about things like data bases, their proposal
7 expresses some hospitality to uses of those kinds of things.

8 But essentially under the F.D.A. system they are
9 going to be accepting the value that you put on your label.
10 They are not going to be prior approving it or looking for
11 data up front. Then they are going to be monitoring compli-
12 ance within this 20 percent margin of error.

13 In terms of what happens next, obviously what
14 happens on the F.D.A. rule is going to be important. We have
15 continued to talk with them on all the different levels. This
16 is an attempt at a joint effort, an attempt to limit the amount
17 of discrepancy that would exist in the two systems; but at the
18 same time past a certain point, we do have independent
19 authority and we do have the ability to disagree with one
20 another.

21 Number two, through that process with F.D.A. and
22 on all sorts of formal and informal levels we are continuing
23 to get input from people and input from groups such as this.

24 And number three, we are going to have to make
25 some decisions in this area as to what approach we will take,

1 both in terms of some substantive decisions such as serving
2 size questions, additional questions about claims. We'll have
3 to decide upon a procedural vehicle for doing that, be that
4 something informal such as the issuance of informal guidelines
5 or, at least conceivably, engaging in our own rule-making
6 process.

7 DR. BRICKENKAMP: Excuse me, I have a question.

8 The question of nutrition labeling, are there any
9 standards at the Federal government level, either F.D.A. or
10 U.S.D.A., for what are the minimum things to be in a nutrition
11 statement?

12 MR. HIBBERT: Yes. F.D.A. has a specific regu-
13 lation on that and addresses a nutrition label with some
14 specificity. We do not have our own nutrition labeling
15 regulations. We do essentially follow the F.D.A. scheme of
16 things, although we approve a lot of labels with short format,
17 with just macronutrients without a complete specification of
18 micronutrients.

19 DR. ALFIN-SLATER: Do you have a mechanism for
20 monitoring all of these labels to see that when somebody says
21 35 milligrams per serving, it actually is 35 milligrams?

22 I say this because I walked here from the downtown
23 airline terminal and saw two health food stores with big
24 letters that said, "We have starch block."

25 I know that the F.D.A. has recalled these. I

1 thought it illegal to sell, but they're selling them.

2 DR. HOUSTON: Well, I can't comment on foods that
3 aren't under our jurisdiction or that may be under local
4 control.

5 Going back to what we talked about a few minutes
6 ago on the prior label approval will answer your question as to how
7 we control 35 milligrams per serving, or 35 milligrams per
8 hundred grams. When that label comes in and that declaration
9 is made, that product is not yet being produced until the
10 label is approved. Included with it is a formulation state-
11 ment as well as laboratory data or Handbook 8 data or some other
12 data that will support the claim.

13 By looking at the formulation and the
14 data, we can then judge as to whether or not that claim is
15 valid. If it is, we will then let that product be produced.

16 Our inspectors are required to see that the
17 companies maintain consistency; that they do formulate
18 products in line with the approved formulation. If they do
19 that, the claim itself should remain valid.

20 In addition, we will take verification samples
21 from time to time to be sure that they're within
22 some acceptable variation.

23 So it's an inplant inspection program formulation
24 controls coupled with some laboratory verification testing
25 that assures that those products going on the market are

1 truthfully labeled.

2 DR. BURNETTE: Don, is there any discussion or
3 probability, there's always a possibility, of joint hearings
4 on this with F.D.A.?

5 DR. HOUSTON: Well, I don't know if F.D.A. is even
6 going to have hearings. They're going through rule making.
7 I don't think we're going to comment on that rule. We're
8 going to leave that up to the public and to the affected
9 parties.

10 We're of course very interested. As I said, we
11 want to be as consistent as we possibly can with F.D.A. We
12 don't think consumers should be subjected to different label
13 claims and different statements. It gets confusing, and it's
14 poor public policy to do that.

15 But as we have in nutrition labeling, we have not
16 adopted the F.D.A. rules. We utilize them; but we're much more
17 flexible, and as a result I think we get much more nutrition
18 labeling even if it's in an abbreviated form sometimes.

19 DR. WILSON: Bob, I think you clarified this,
20 perhaps if you did I didn't like what I heard.

21 Relative to milligrams per serving when you were
22 saying simple labeling, you indicated that milligrams per
23 serving were in order, but on the U.S.D.A. slide you showed
24 in claims that you would require in milligrams per hundred
25 gram. This strikes me as being rather inconsistent with the

1 two declarations.

2 MR. HIBBERT: I'm saying there is an inconsistency.
3 There's F.D.A. going out now and posing that the system be
4 changed to per serving, and we're still working off the hard
5 number of per hundred grams.

6 DR. WILSON: But you weren't consistent within your
7 own policy, though.

8 MR. HIBBERT: No. Thirty-five milligrams per
9 hundred grams as a maximum for a low sodium claim is our
10 policy.

11 DR. WILSON: And simple labeling is milligrams per
12 serving, is your policy. That's what I'm trying to clarify.

13 On your U.S.D.A. slide you showed two declarations
14 for sodium, one in milligrams per serving for a simple
15 declaration. Down in category two you had claims --

16 MR. HIBBERT: Okay. We'll put that slide back on.

17 (The slide was again shown to the Committee.)

18 Yes. The distinction as between the flat statement
19 of content and the claim.

20 DR. WILSON: Yes.

21 MR. HIBBERT: In terms of the statement of content,
22 yes, and arguably that is not entirely consistent. But for
23 statement of content, we require that you declare your milli-
24 grams per serving. In terms of when you are eligible to make
25 a claim such as low sodium, that is geared not to serving but

1 to hundred grams.

2 DR. WILSON: I was hoping I didn't understand that.

3 MR. MC DADE: Did I understand this right, then,
4 that low sodium to the U.S.D.A. is 35 milligrams per 100 grams,
5 and since normally a serving is two ounces in most cases, to
6 F.D.A. it's 35 milligrams per 56.7 grams. It's almost twice
7 as much for F.D.A.; is that correct?

8 MR. HIBBERT: Of course it's a little tricky
9 because while that's a serving size, it's not the only serving
10 size, and that's where you get into some complications about
11 what is a serving size.

12 We do not have, neither we nor F.D.A. has hard
13 definitions on the books as to what is a serving size, and
14 that's where you start to incorporate some mischief into the
15 mathematics here when you start to move the size of the
16 serving size around.

17 MR. MC DADE: It seems that most serving sizes are
18 around two ounces, and it seems to me these would almost be a
19 hundred percent apart, then, per hundred grams.

20 DR. HOUSTON: Well, that's the reason for the
21 arguments that are going on.

22 DR. FOSTER: I don't know where you get that two
23 ounces as most serving sizes. I've got a table right here
24 from the Atlanta paper yesterday with about 25 items listed,
25 source, U.S.D.A. Handbook No. 456, and the serving sizes range

1 from a teaspoon to eight ounces, a pint.

2 MR. MC DADE: A teaspoon of poultry?

3 DR. FOSTER: No, no, get poultry off your mind.

4 These are serving sizes.

5 MR. MC DADE: But normally in the nutritional
6 labeling that I've worked with on, it certain does not have
7 to be two, but I'm saying that these seem to be further apart
8 than I considered them being when I first read it through.

9 The F.D.A. and U.S.D.A. are considerably apart.

10 DR. BURNETTE: Luncheon meat is one ounce. There's
11 four times the difference.

12 MR. MC DADE: A frankfurter is four ounces.

13 DR. BURNETTE: This is tomorrow, isn't it?

14 DR. HOUSTON: I hope so.

15 Does anyone else have a question in this area
16 before we proceed?

17 Okay. We've been sitting here for two hours, let's
18 take a break and come back at 3:15 p.m., please.

19 (Whereupon a 20-minute break was taken.) .

20 DR. HOUSTON: Let's reconvene the meeting.

21 We're scheduled to be out of here by 5 o'clock so
22 we'll have to move through the next several areas but I think
23 we'll be able to do it.

24 We'll be talking about Continuous Inspection,
25 Import Inspection, Food Safety Legislation, and the Food

1 Safety Poster Contest for the remainder of the afternoon.

2 LESS-THAN-CONTINUOUS INSPECTION

3 Let me take a few minutes at this point and talk
4 about Less-Than-Continuous Inspection, or as it's sometimes
5 called, Discretionary Processing Inspection.

6 We talked about this last year when the Committee
7 was together, but there's been a number of actions
8 since then and for the new members I'll get into some of the
9 background.

10 Legislation has been introduced in the House and
11 Senate to amend the Federal Meat Inspection Act and the
12 Poultry Products Inspection Act to give the Secretary of
13 Agriculture broader discretion in determining the intensity
14 of inspection provided to individual meat and poultry proces-
15 sing plants. I believe copies of the House and Senate bills
16 were provided to you in your information package.

17 The proposed changes would give the Secretary
18 authority to adjust the staffing of inspection personnel in
19 processing plants based on the compliance history of the
20 company, the degree of public health risk associated with a
21 given type of product, the quality of the company's own inplant
22 monitoring system, and other factors the Secretary deems
23 appropriate. There's been some question about what these
24 other factors are, but they relate principally to criminal
25 involvement and when we find that, we would have the

1 authority to take action to increase intensity of inspection,
2 regardless of what other factors might be taken into consider-
3 ation.

4 Hearings on the proposal have been scheduled for
5 August 10 before the Subcommittee on Livestock, Dairy and
6 Poultry of the House Committee on Agriculture. That
7 particular Subcommittee is chaired by Congressman Tom Harkin
8 if Iowa. We feel fairly confident at this point that we will
9 also have hearings sometime in August or at least within this
10 session of Congress by the Senate Ag Committee, but there has
11 been no date set at this point.

12 Under the law as it is now written, Federal
13 inspection is provided on a daily basis in all processing
14 establishments. Under the proposed amendments, the Secretary
15 would have discretionary authority to determine, on a plant-by-
16 plant basis, the appropriate level of inspection in processing
17 plants. It should be emphasized that the proposal to give the
18 Secretary discretion in determining the frequency and extent
19 of inspection would apply only to the inspection of processed
20 meat and poultry products. It would not affect slaughter
21 inspection. An inspector would still be required to be
22 present during all slaughter operations and to inspect every
23 livestock or poultry carcass.

24 The language of the Federal Meat Inspection Act
25 states tha inspectors will "mark, stamp, tag or label as

1 'Inspected and passed' all meat food products," and applies to
2 both slaughter and processing inspection. A narrow interpre-
3 tation of the language could mean that a U.S.D.A. inspector
4 must personally inspect every frankfurter, piece of luncheon
5 meat, and pork chop before it could be "Inspected and passed"
6 and that an inspector must personally place every label, mark,
7 stamp, or tag on each item.

8 The Department has never interpreted the language
9 so narrowly since to have done so would have created enormous
10 costs without significantly increasing the effectiveness of
11 inspection. Instead, it was decided that the Act called for
12 the daily, continuous presence of Government inspectors in
13 both processing and slaughter establishments. This position
14 is supported in the legislative history of the Meat Inspection
15 Act and the Federal Meat Inspection Act, as well as by sub-
16 sequent opinions of the Department's General Counsels over a
17 number of administrations.

18 From 1946 to 1976, total meat production doubled,
19 but the production of further processed meat almost quadrupled.
20 Recent years have witnessed an increased demand for processed
21 convenience foods served in the home, and a large part of the
22 population regularly eats at fast-food restaurants supplied by
23 the meat and poultry processing industry.

24 During the years when the processed food industry
25 was growing rapidly, many processors tended to rely on U.S.D.A.

1 inspectors to control the quality of their products. Some
2 companies eventually realized, however, that to fulfill con-
3 sumer expectations they would need more sophisticated pro-
4 cedures for controlling production and began designing systems
5 specifically for controlling the production process. These
6 systems, generally called "process quality control," were
7 designed to provide consistent and uniform products that were
8 produced at predictable costs and that met Government
9 regulatory requirements.

10 During the las decade the number of Federally
11 inspected meat and poultry processing plants increased 60
12 percent, from 4,200 approximately in 1971 to 6,821 in 1981.
13 The figure 7,000 plus that I used a while ago, of course,
14 included slaughter plants.

15 In the same period, the volume of Federally
16 inspected processed product increased 48 percent, reaching
17 about 105 billion pounds for 1981. The total cost of pro-
18 cessing inspection has increased from \$28 million in 1971 to
19 \$76 million in 1981. In fiscal year 1981 processing inspection
20 accounted for 26 percent of the total F.S.I.S. budget.

21 The large number of plants under inspection strains
22 the use of resources because of the necessity of providing
23 daily inspection to plants whose production or product com-
24 plexity may not justify the assignment of a full-time in-
25 spector. To cope with the problem, U.S.D.A. has established

1 "patrol" inspection. Under that patrol system, inspectors do
2 not spend a full day in an establishment but are responsible
3 for several plants within a geographical area and visit each
4 plant at least once a day. About 55 percent of processed meat
5 and poultry production now under Federal inspection is in-
6 spected on a patrol basis.

7 Although patrol inspection and other management
8 innovations have enabled U.S.D.A. to restrain the growth in
9 the number of processing inspectors to only 10 percent over
10 the last decade despite the 60 percent increase in the number
11 of Federally inspected establishments, in many ways this
12 inspection system is inefficient. Transportation costs are
13 high, and large amounts of an inspector's time are devoted to
14 nonproductive travel. Although the growth in the number of
15 processing inspectors has been curbed, overall personnel costs
16 have escalated dramatically during the period because of
17 inflation.

18 In its 1977 report entitled "Study of the Federal
19 Meat and Poultry Inspection System" a consulting firm commis-
20 sioned by U.S.D.A. recommended that the Department, to reduce
21 inspection costs, adopt a monitoring approach to inspection,
22 relying on processors' quality control records as part of an
23 inspection technique. The monitoring by inspectors of quality
24 control records would be combined with verification samples
25 and plant visits to ensure compliance with Federal regulations.

1 In essence, the study recommended that industry assume the
2 primary responsibility for providing evidence that it was
3 meeting regulatory standards.

4 If the quality control method of inspection were
5 adopted, the study estimated, U.S.D.A. would achieve major
6 savings through a reduction in the total number of inspectors.
7 At the same time, the Department would gain increased flex-
8 ibility in the use of its inspection resources and would be
9 able to focus on problem areas. The report also predicted
10 that the cost to industry of establishing quality control
11 programs would be offset by reductions in product defects and
12 production down-times and by the elimination of overtime costs
13 for inspectors.

14 In December of '77 the General Accounting Office
15 issued a report entitled "A Better Way for the Department of
16 Agriculture to Inspect Meat and Poultry Processing Plants"
17 which recommended that U.S.D.A. inspectors monitor industry-
18 operated comprehensive quality control systems by making
19 periodic, unannounced visits, submitting samples of finished
20 product for laboratory testing, and checking company records.
21 In addition, G.A.O. recommended that the frequency of inspection
22 be tailored to individual plants.

23 In a 1981 report entitled "The Department of
24 Agriculture Should Have More Authority to Assess User Charges"
25 the G.A.O. endorsed its earlier proposal that U.S.D.A. adopt a

1 system of periodic, unannounced inspections coupled with
2 implant quality control programs. Moreover, G.A.O. urged the
3 Congress to amend the Federal Meat Inspection Act and the
4 Poultry Products Inspection Act to allow the Secretary this
5 method of processing inspection.

6 In the last several years the Department has,
7 through restructuring and development of new methods, taken
8 steps to modernize meat and poultry processing inspection and
9 hold down costs. However, we can only go so far to reduce
10 costs, however, without sacrificing effectiveness -- par-
11 ticularly in slaughter inspection -- so the Department has
12 looked to changes in processing inspection as a safe and
13 appropriate way to increase efficiency.

14 Since the 1960's the Department has recognized the
15 value of encouraging industry to develop partial quality con-
16 trol programs over key production processes as a means of
17 improving inspection. Currently, over 700 meat and poultry
18 processing plants have instituted more than 2,300 partial
19 quality control programs. Examples of these programs include
20 time and temperature control, net weight, nutritional labeling,
21 and fat and added water controls.

22 Perhaps the most far-reaching response of U.S.D.A.
23 to the changing trends in meat and poultry processing has been
24 the development and implementation of the voluntary Total
25 Quality Control system, which grew from the expanding partial

1 quality control programs. On August 15, 1980, the Department
2 published regulations on voluntary total quality control
3 systems for meat and poultry processing plants.

4 Under the T.Q.C. program, plant management develops
5 a plan that establishes organized controls at each critical
6 phase of product handling and processing. The Department
7 evaluates the plan to assure that the system will consistently
8 produce products in compliance with regulatory requirements.
9 Once a plan is approved, U.S.D.A. inspectors trained in T.Q.C.
10 inspection monitor the data generated by the system.
11 Inspectors also conduct their own independent observations and
12 draw samples for verification testing in U.S.D.A. laboratories.

13 Our experience with T.Q.C. has shown that it is
14 not always necessary for Government to act as industry's
15 quality control system. Industry for its part has proved
16 that it can and will assume its share of responsibility for
17 producing products that are safe, wholesome, and in compliance
18 with regulatory requirements.

19 It should be emphasized that the proposed legis-
20 lation places no new requirements on the regulated industry.
21 It does not impose mandatory quality control systems, but is
22 limited to giving the Secretary increased flexibility in using
23 inspection resources, based on sound criteria. While it is
24 true that the bill would permit the regulatory burden to be
25 eased in plants operating good quality control systems, the

1 decision to implement such systems remains totally with the
2 industry.

3 Participation in the Department's voluntary T.Q.C.
4 program constitutes only one of the factors that would be
5 used to determine eligibility for less-than-continuing in-
6 spection. As required under the bill, the kind of processing
7 operations involved and an establishment's compliance history
8 would be equally important considerations. Finally, the
9 management's attitude toward and ability to deal with
10 sanitation and other product safety requirements would be
11 considered.

12 If the discretionary processing legislation were
13 enacted, the major difference would be that the Department
14 would have the authority to determine the nature and frequency
15 of inspection at each processing establishment and would no
16 longer arbitrarily be locked into providing continuous in-
17 spection to processing plants. In those cases in which plant
18 management has demonstrated that it is both willing and able
19 to assume a greater share of responsibility for product com-
20 pliance, it is not necessary for the Department to inspect the
21 plants on a daily basis. The legislation would enable the
22 Department to develop a more rational system of inspection
23 than is now possible and to tailor that system to actual
24 inspection needs.

25 Are there any questions on that?

1 Dr. Wilson.

2 DR. WILSON: I have a question, not on the specific
3 area that you've already mentioned but it's relative to the
4 change, the suggested change at least in the logo which would
5 go with less-than-continuous inspection, indicating that the
6 product was prepared in a U.S.D.A. inspected and passed plant
7 as contrasted to U.S. inspected and passed.

8 I review the proposed change as a delegation of
9 responsibility to the plant, or at least I think that's
10 implied, very much like the T.Q.C. program you were just
11 describing. If under the T.Q.C. program the plant still can
12 retain U.S. inspected and passed, and you're suggesting that
13 T.Q.C. would go hand in glove with reduced inspection. I don't
14 follow the rationale for and perhaps you could explain the
15 rationale for changing the logo.

16 My concern for that is that. I think we've worked
17 for many years in the industry to get the consumer to under-
18 stand what U.S. inspected and passed is. She's still mixed up
19 with what that means versus the grading stamp. We don't really
20 see it being desirable to introduce another stamp.

21 Perhaps you could explain why you think there's a
22 need for it.

23 DR. HOUSTON: I didn't cover that point, but as
24 further clarification, Dr. Wilson is pointing out that the
25 bill language would change the inspection legend to read

1 from "U.S. inspected and passed" to "prepared in a U.S.D.A.
2 inspected plant."

3 I think it goes back to what I mentioned earlier
4 that there's no way that we can inspect every frankfurter,
5 every piece of meat, every package that leaves the plant. To
6 some people that implication is there in the current inspection
7 legend; U.S.D.A. inspected and passed implies to someone
8 buying a package of frankfurters that
9 everyone of them was personally inspected and checked and
10 passed by U.S.D.A. inspector. That's certainly not the case,
11 and those of you familiar with food processing operations know
12 that it would be an impossible task to do that.

13 So we took the opportunity to get away from that
14 language and to at least propose language that was
15 more consistent with what we are doing, which is that we're
16 inspecting that plant, and that it was prepared in a U.S.D.A.
17 inspected plant, and not necessarily the product being inspected.
18 Because that's really how we're operating. I think it would
19 be better language if we go to less-than continuous in-
20 spection.

21 These products would still be coming out of U.S.D.A.
22 inspected operation.

23 We don't consider that a critical
24 point in the bill. We've never felt that language should be
25 considered necessary in order to get that bill passed. If the

1 Congress and others in their wisdom as we hold hearings on this
2 bill, feel that there are better ways to resolve that problem,
3 I think the department is certainly willing to consider other
4 language.

5 But for purposes of clarification, those are our
6 reasons, Dr. Wilson. The bottom line is that we are quite
7 willing to consider other language at such time as we have
8 hearings on this matter.

9 Dr. Burnette.

10 DR. BURNETTE: I understand that the intent is to
11 continue 100 percent inspection for pre-mortem and anti-mortem
12 slaughter and only go to phase inspection for the processing.

13 DR. HOUSTON: That's correct.

14 DR. BURNETTE: In reading the language of the
15 proposed legislation, there is language in there which says
16 that there are products that are in slaughter plants or what-
17 ever.

18 Am I correct that by not having the legislative
19 language pertain to Sections 3, 4 and 5, that that puts it
20 exclusively in further processing and leaves all pre and post
21 slaughter inspections untouched even though slaughter establish-
22 ments are mentioned in Section 6? It doesn't pertain to
23 slaughter inspection?

24 DR. HOUSTON: You're correct, and the reason the
25 language is written that way is because processing operations

1 are sometimes carried out at slaughter establishments, and
2 that is the reason for that language, to be sure that those
3 operations which are considered further processing in slaughter
4 establishments, under the same roof if you will, will be
5 subject to the discretionary authority that this bill would
6 give to the Secretary. That's why that language was written
7 that way.

8 It's been confusing to a number of people who have
9 read it because they immediately draw the conclusion that it
10 means slaughtering, but it doesn't. It only means those
11 operations that are considered processing in plants which also
12 conduct slaughtering. It's to clarify that point.

13 You're absolutely right. It would not cover ante-
14 mortem and post-mortem inspections.

15 DR. BURNETTE: I understand what you just said.
16 I'm really asking, and I think you answered it, about the
17 obverse of that, and that is by making no mention of 3, 4 and
18 5, then legally they remain unchanged.

19 DR. HOUSTON: I'd have to look at the law again
20 before I'd say with finality I agree, but I believe you're
21 correct. I'll check into that tonight and talk to you about
22 it tomorrow, but I'm quite sure that's the case.

23 DR. BURNETTE: Is there some way in Title 1 of the
24 new proposed legislation that you could put a sentence in there
25 saying that 3, 4 and 5, pre- and post-mortem slaughter

1 inspection aren't going to be changed so that then when you go
2 to the other part, it'll be obvious you're not talking about
3 that.

4 DR. HOUSTON: If you feel that's necessary, we can
5 certainly consider it. The bill of course was written by the
6 Department's general counsel with the full understanding of
7 what our policy implications were intended to be. They assured
8 me this was the case. But if you feel it needs
9 strengthening in that area, we can certainly do so.

10 DR. BURNETTE: It's just confusing.

11 DR. HOUSTON: I agree with you.

12 MS. VISSIER: The language is not in here, I don't
13 think, it may not be appropriate in the law. It maybe that
14 it should be in rule making. Will the point at which further
15 processing begins be spelled out?

16 DR. HOUSTON: Yes, it will, but again that will
17 have to be done in rule making. We would not want to get that
18 specific in the law because then it inevitably creates pro-
19 blems in the future.

20 Our present thinking is that it would be any
21 procedure that occurred after post-mortem inspection is com-
22 pleted. In poultry plants, with which you're familiar, that
23 would include chilling, for example. In red meat plants it
24 would include inspection of coolers.

25 DR. BURNETTE: Those would be part of the allowance

1 for phased inspection?

2 DR. HOUSTON: That's correct.

3 DR. BURNETTE: So you'd be inspecting records.

4 DR. HOUSTON: Plus other things. You'd be doing
5 record checks; you'd be making visual observations, and also
6 taking verification samples. It's more than just a records
7 review.

8 Mr. Carbaugh.

9 MR. CARBAUGH: Just a question, Dr. Houston. Did
10 you folks discuss the inclusion of a penalty provision for
11 noncompliance in this bill, and if so, could you enlighten me
12 on the background of that?

13 DR. HOUSTON: Yes, we did talk about civil
14 penalties and chose not to include them in this
15 bill. There were several reasons.

16 First this bill does not weaken the inspection
17 system as we know it today, and to include civil penalties
18 would infer that we're doing so. We believe if the quality con-
19 trol system would be utilized, is at least effective or more
20 effective, than the present system we have today. It's a much
21 more objective system. It generates much more data for the
22 inspector to review than the present system does. It's much
23 more systematic. Just generally, we think it does a better
24 job based on the experience we've had to date.

25 So I would not want to bring in civil penalties as

1 a way of saying that this system is worse than the present
2 system. It's a better system, so I don't think we need
3 civil penalties.

4 We think the present penalties that are available
5 to the Department are adequate. Those penalties include the
6 authority for inspectors on site to retain or condemn product, to
7 reject rooms. We have the authority to detain product outside of
8 a plant. We have the authority to ask for seizure action in a
9 Federal court. We have certain administrative sanctions
10 such as removal of inspection. We can prosecute people,
11 which we do. We can ask for Federal courts to issue
12 injunctions.

13 We have a whole range of sanctions that we can
14 rely upon based on the situation that we must face. It is for
15 that reason that civil penalties were not necessary.

16 But most importantly we did not want to leave the
17 impression that we were weakening an inspection system by having
18 to include additional penalties.

19 MR. CARBAUGH: One more question. What happens
20 when you have a situation where you have less-than-continuous
21 inspection and you find noncompliance? What do you do then?
22 Do you go back to full inspection?

23 DR. HOUSTON: I think it depends on what degree of
24 noncompliance occurs. That is one possibility. Noncompliance
25

1 can occur from a very minor violation to one which could result
2 in a criminal action. So I think we have to look at each one
3 individually and judge it. But if it were serious enough and
4 there was some evidence of a history of noncompliance, as I
5 pointed out, that's one of the criteria, we could go back to
6 continuous inspection where we could no longer place any
7 reliability on that plant, and we would have to be more intense
8 in the level of inspection required. That is one option and
9 probably the option we'd take.

10 We could also, if it were serious enough, prosecute
11 the company involved.

12 MR. CARBAUGH: Did you consider the possibility of
13 charging that plant for that additional inspection?

14 DR. HOUSTON: The user fees?

15 MR. CARBAUGH: Yes.

16 DR. HOUSTON: Yes, sir, we did. The present
17 position of the Department of Agriculture is that it strongly
18 opposes users fees in carrying out the meat and poultry in-
19 spection program under any set of circumstances for a variety
20 of reasons, and we can get into those.

21 But we do not want to open that door to user fees
22 under any condition if we can avoid it.

23 MR. CARBAUGH: Not even in a limited way?

24 DR. HOUSTON: At this point we're not prepared to
25 do so.

1 MR. CARBAUGH: I might say more about that
2 tomorrow.

3 DR. HOUSTON: Dr. Burnette.

4 DR. BURNETTE: Just since the compliance clauses
5 came up, I guess four years ago when there was serious con-
6 sideration in both Houses of Congress of revisions of Food,
7 Drug and Cosmetic Act, one of the things that was discussed
8 was for inflation reasons if nothing else, including the
9 existing F.D.C.A. dollar penalties to make them more commensu-
10 rate with the Act, I suppose if you will. Now those provisions
11 never passed; it never happened.

12 Has there been any discussion of taking the op-
13 portunity in this bill to modify Section 406 to increase the
14 cap of \$1,000 on meat and poultry and egg inspection pro-
15 visions to make them more commensurate with the Act as Mason
16 was asking?

17 Has there been any discussion of doing that in
18 conjunction with these amendments?

19 DR. HOUSTON: Well, I don't have the law in front
20 of me, but we have authority to go far beyond \$1,000. That
21 maybe for a specific set of actions there. I'm not familiar
22 with that.

23 DR. BURNETTE: That's for the non-specific.

24 DR. HOUSTON: For example, I think the limit on
25 fines is \$10,000, and incarceration can be included many times

1 as well.

2 DR. BURNETTE: Right, up to three years. It's the
3 same in the Food, Drug and Cosmetic Act and this was four years
4 ago. Both Houses of Congress had pretty well decided if they
5 moved the bill, they were going to move to put the F.D.C.A.
6 cap up to \$25,000, \$10,000 not meaning much to most corpo-
7 rations, in their opinion.

8 So since there are a lot of the same Congressional
9 members there, I'm just asking, has there been any discussion
10 of the same thing on this bill?

11 DR. HOUSTON: To answer your question, there has
12 not. There has been no consideration.

13 Any other questions on that particular area?

14 IMPORT INSPECTION

15 Let's turn to Import Inspection. There are a
16 couple of slides that I want to start with before I get into
17 some of the text.

18 What I'd really like to do is just bring you up-to-
19 date on where we are in making certain changes in our Import
20 Inspection program. But before I do that, I've got a couple
21 of slides that I'd like to show you, just to put into focus
22 where we are with imported meat coming into the United States.

23 (The first slide was shown to the Committee.)

24 Just as some background, the leading countries
25 that are bringing imported meat into the United States -- and

1 I'll limit this to meat because there is little or no poultry
2 that enters the United States -- the five leading countries
3 are right there. Obviously Australia and New Zealand are
4 leading the way. They supply principally fresh-frozen, bone-
5 less meat which goes for manufacturing purposes into the
6 production of frankfurters and hamburgers and things of that nature.

7 Canada ships to us a whole variety of meat-food
8 products, fresh products as well as processed products.

9 The principal item coming out of Denmark of course
10 is canned, cured pork products.

11 There is some boneless meat coming out of Costa
12 Rica.

13 Also another large supplier of cured pork products
14 to the United States, probably just under Costa Rica in terms
15 of volume is Poland.

16 (The next slide was shown to the Committee.)

17 Principally two items come into the United States,
18 fresh meat which is frozen and again as I pointed out, that
19 comes from Australia and New Zealand. The other products are
20 canned, cured pork products, canned ham, pork shoulders, and
21 those come from Denmark and Poland, who are the two largest
22 suppliers into the United States.

23 (The next slide was shown to the Committee.)

24 In 1981 we had about 1.8 billion pounds of imported
25 products offered for entry, and of that 11 million rejected

1 for a number of reasons, but usually it's foreign material,
2 filth, sometimes underweight, but generally in those three
3 areas. So you can see as a percentage it's a rather low
4 amount.

5 (The next slide was shown to the Committee.)

6 In terms of what that means to our domestic meat
7 supply, with regard to carcass weight -- I'm not going to
8 read those numbers -- but imports as a percent of our total
9 meat supply run around 7 percent a year. But for pork products
10 it will be less than that, obviously they're lesser in volume.
11 For beef it'll probably run close to 10 percent of the beef
12 supply, something along that area. But an average of about
13 7 percent for all meat after you factor everything in.

14 (The next slide was shown to the Committee.)

15 Last year when the Committee met, we had just com-
16 pleted what was then known as the horse meat and kangaroo
17 scandal. In July of last year we discovered a clan-
18 destine operation being carried out in Australia in which
19 product was being reboxed or relidded and offered for entry
20 into the United States as boneless beef. Fortunately a very
21 alert inspector in Los Angeles picked that up and we were able
22 to get on to it rather early.

23 I spent the entire month of December last year in
24 Australia reviewing the new systems that the Australian govern-
25 ment had put in place to preclude another problem.

1 In doing so, they discovered that they had far more
2 serious problems than they had originally suspected. Most of
3 it revolved around the fact that there are many sources of
4 meat that we would consider exotic, exotic to the United
5 States, but many available sources of it in Australia. It is
6 traded quite freely.

7 They've also found out since this scandal broke
8 that a lot of this product has been going into countries,
9 especially in Asia and other areas where they do not have
10 adequate inspection systems. It has been going in there quite
11 freely, mislabeled as beef.

12 This is just an example. I was going through cold
13 stores in some of their large cities. It's not uncommon to
14 see boneless buffalo meat like this, which is water buffalo.
15 It's not the kind of buffalo we have here in this country.
16 But you'll see huge amounts of this.

17 I can't tell you where it all goes. But it's very
18 easy right there to take that box top off and put a new one on
19 it with a new label, and right away you've transformed boneless
20 buffalo meat into boneless beef. Of course, that's what had
21 been going on. They tried to get it into the United States
22 and fortunately we caught it.

23 This product is very evident all over the country.

24 (The next slide was shown to the Committee.)

25 This is another cold store which shows kangaroo

1 meat in storage. Again, there are enormous amounts of this product
2 available because you've got millions of kangaroos and they're
3 field killed and dressed and brought into central areas . . .
4 where the meat is boned and packed.

5 I can't tell you where all of this goes. Some of
6 it goes into the pet food industry. I think there's very
7 little of it coming into the United States, but it goes some-
8 where.

9 DR. ALFIN-SLATER: Is there anything wrong with it?

10 DR. HOUSTON: Well, it's hard to say.

11 MR. LOUNSBERRY: When it's slaughtered and pro-
12 cessed, yes.

13 DR. HOUSTON: That's the problem. You don't know
14 the conditions under which the animal was slaughtered, whether
15 it was a healthy or sick animal. Many times because they are
16 field dressed, they're contaminated with filth and dirt. You
17 have no knowledge, really, as to the quality of meat because
18 there's no way to determine.

19 You can, of course, inspect it; you can open it up
20 and check for filth and so forth.

21 But under our law, of course, by bringing that
22 product in as beef it was mislabeled, obviously.

23 (The next slide was shown to the Committee.)

24 This is prime kangaroo meat. I don't know what
25 "prime" is.

1 MS. MUCKLOW: How did it taste?

2 DR. HOUSTON: I didn't eat any of it.

3 ('The next slide was shown to the Committee.)

4 You may not be able to see this very well, but this
5 is some product from a company called Jason's Meats, which was
6 establishment 622, which was one of the companies that we
7 found had gotten product into the United States that was labeled
8 boneless beef but in fact was kangaroo meat.

9 I just happened to be in a cold store and this
10 product is under control of the Australian Federal Police,
11 and although it is labeled boneless beef, it's all kangaroo
12 meat and horse meat, and they were getting ready to ship it
13 over here when the scandal broke. It was under control and is
14 going to be used as evidence in some trials.

15 Since then they've held the trial and the person
16 who owned the meat has been sentenced and I suppose this meat
17 has been disposed of since then.

18 That's the kind of thing that was going on.

19 Now as a result of that scandal and the recent
20 problems we've had with the product coming in from Costa Rica,
21 which was outlined to you in materials that was sent to you,
22 and that was principally a problem of poor control of export
23 certificates by the Costa Rican government, we've done a
24 number of things and I'll go over those rather quickly.

25 A number of steps have been taken in recent years

1 to strengthen and improve the U.S.D.A. inspection program for
2 imported meat. These efforts began in 1979, when the Depart-
3 ment began to take a close look at the underlying philosophies,
4 policies, and procedures for inspecting imported product.

5 It is clear that recent incidents, such as those
6 involving Australian and Costa Rican meat, have jeopardized
7 consumer confidence and the corresponding economic health of
8 the industry. You have copies of background papers and press
9 releases on these incidents in the background material which
10 was provided to you several weeks ago.

11 I believe we moved quickly and responsibly in
12 response to the Costa Rican and Australian crises and am
13 certain that under our improved program for imported meat the
14 need for reactive clean-up efforts such as those that took
15 place in these cases will be significantly reduced.

16 We are building into our program a preventive
17 approach to import inspection which should further ensure that
18 the produce we import from our foreign trading partners meets
19 the same high standards as that produced in the United States.

20 In 1979 an Agency task force proposed that foreign
21 meat inspection efforts be redirected from the historical
22 focus on individual plants to a broader look at the reliability
23 of a country's regulatory program. That is, plant-by-plant
24 reviews should only be part of a process that systematically
25 evaluates the entire regulatory control system within that

1 country. A second recommendation was that these efforts be
2 accomplished by more objective and specific measures of per-
3 formances.

4 I might say parenthetically here that we do
5 require and have always required that a foreign country's
6 inspection system be equal to that here in the United States.
7 That is required by law, and we evaluate on that basis.
8 However, we have limited our evaluation for the most part to
9 inspection performance in plants. We have never taken the
10 look that should have been taken at regulatory controls
11 regarding the movement of such things as pet food, and the
12 types of programs or compliance efforts that these countries
13 have in place to find out where criminal activity is occurring.

14 As a result of the 1981 Farm Bill, on July 8, 1982,
15 we published in the Federal Register a proposal which
16 codifies existing requirements providing that standards ap-
17 plied to foreign products offered for importation into the
18 United States are at least "equal to" the standards applied
19 to domestic products. An additional proposed amendment would
20 require foreign countries desiring to establish and/or maintain
21 eligibility for importation of products into the United States
22 to have and maintain a program to test for residues in the
23 internal organs and fats of carcasses from which food products
24 intended for export to the United States are produced.

25 I might say that's still an administrative

1 requirement at this point. However the 1981 Farm Bill puts
2 that into legislation.

3 Copies of the proposed rule have been distributed
4 to you.

5 Comments on that rule will be accepted through
6 September 7 and then will be reviewed and evaluated. Formal
7 rule-making procedures aside, however, specific actions have
8 been and are being taken to improve the import inspection
9 program. To follow up on the task force review that I
10 mentioned, the Agency in 1981 published guidelines to measure
11 a country's ability to control six basic risk areas: bio-
12 logical residues, disease, misuse of food additives, gross
13 contamination, microscopic contamination, and economic fraud.

14 Data collection has begun, starting with the
15 countries supplying the largest percentage of imports. When
16 necessary, this data will be supplemented by onsite verifica-
17 tions. Plans call for implementation of the new approach,
18 including ongoing reviews by the Agency, by the end of the
19 fiscal year 1983.

20 Last year's Australian meat substitution scandal
21 spotlighted a critical area to be addressed within the Agency's
22 new approach: product integrity, that is, the controls a
23 foreign country exercises to prevent the introduction of
24 illegally prepared or unauthorized meat into export channels.
25 We expect to integrate these controls into the system by the

1 end of this fiscal year, 1982.

2 On November 13, 1981, we sent a cable to all
3 certified countries stating two additional eligibility require-
4 ments for exporting product to the United States: (1) species
5 testing programs, and (2) compliance controls to assure product
6 integrity. The cable requested that all data concerning these
7 areas be sent to the Agency earlier this year.

8 Regarding the species testing program requirement,
9 the large suppliers of boneless meat have complied with this
10 request. The smaller suppliers are coming into compliance.
11 We will continue to push this requirement aggressively.

12 And I might add that I have reviewed the information
13 from Australia where the problem first surfaced, and we've
14 concluded that sufficient remedies have been implemented in
15 that country.

16 An interdisciplinary team comprised of compliance
17 program and foreign review experts will visit three represen-
18 tative countries to obtain additional information on product
19 integrity controls. The resulting information will be used
20 to design comprehensive review procedures for evaluating the
21 continued effectiveness of compliance programs in eligible
22 countries.

23 We are committed to improving import inspection
24 operations at all import stations, that is, port of entry.
25 Initiatives already underway will improve reporting, sampling

1 techniques, laboratory testing, sample security, and refused-
2 entry product procedures.

3 Each shipment of imported product must pass a port-
4 of-entry examination by F.S.I.S. inspectors before the product
5 is permitted to enter U.S. commerce. The Automated Import
6 Information System, operational since 1979, is a computerized
7 system which tallies and stores daily inspection results by
8 establishment and by country, from all ports of entry. This
9 System enables us to apply a variable inspection format which
10 lets us concentrate resources where they are needed most: on
11 product from producers with inspection histories revealing
12 potential or real problems.

13 The Australian meat incident called into question
14 the range and completeness of port-of-entry inspection con-
15 trols, particularly the Agency's ability to detect species
16 violations and various other types of compliance problems in
17 their early stages. After a thorough review of existing
18 practices, on November 10, 1981, we integrated into the A.I.I.S.
19 a species identification monitoring program. Thus far, all
20 samples taken since that time have been in compliance.

21 The Agency is also conducting an intensified
22 training program to help the inspectors more easily identify
23 what we consider to be illegally prepared meat. As recom-
24 mended by the Agency's Board of Inquiry on the Australian meat
25 incident, we are also working to expand laboratory capabilities

1 through the development of improved species identification
2 tests. The Board's other recommendations also have been
3 adopted. You have been provided a copy of the Board of
4 Agency's report.

5 Through an automatic and systematic review of
6 inspection findings exceeding predetermined levels, the Agency
7 is developing an "early warning" system to flag existing or
8 potential problems, including the illegal preparation of
9 meat. We are also reviewing all import inspection procedures
10 to determine whether they meet today's needs. These review
11 findings will indicate the nature and extent of any needed
12 additional revisions to the Import Information System.

13 Although the shared responsibilities of F.S.I.S.
14 and the U. S. Customs Service have, for the most part, worked
15 well to protect the public from adulterated or misbranded
16 imports, the former procedures did contain certain weaknesses.
17 For example, product lots that were refused entry at one port
18 could be transported to a second port for shipment out of the
19 country. The product was not shipped under seal. At the
20 second port, lots could be subdivided for shipment to several
21 consignees. Under these procedures, we were unable to identify
22 whether an entire lot, or only a portion, had been properly
23 exported or otherwise disposed of.

24 Let me say here that our law does not permit us
25 to condemn product that's offered for entry into the United

1 States and which is refused entry. It has to be destroyed
2 voluntarily by the owner. They do have the right to take the
3 product out of the country, and in many cases they do so.
4 They export the product and sell it at a number of locations.

5 In addition, although regulations required dis-
6 position of the product within 30 days unless an extension
7 were granted, extensions were freely granted. Further, Customs
8 officials were not able to witness the proper disposition of
9 refused-entry products, but instead had to rely upon forms
10 transmitted to them by various brokers, owners, and consignees
11 of the product. As a result, some refused-entry meat and
12 poultry has remained in the United States for two or three
13 years before being exported, with no official record of its
14 location.

15 F.S.I.S. recently issued to import inspectors
16 tightened procedures for marking, controlling, and re-exporting
17 refused-entry product. The Agency is also developing
18 emergency revisions to the regulations to strengthen these
19 procedures further.

20 The most significant change we have made is that
21 the Department will maintain security over all refused-entry
22 product until it is either destroyed, converted to nonhuman
23 food use, or exported. If product is refused entry at an
24 inland inspection location, it must be transported to an ap-
25 proved port under U.S.D.A. seal. Product refused entry at

1 port inspection locations must be exported from ports. In
2 these cases, product must be transported under official seal.
3 In addition, inspection personnel have been instructed not to
4 permit product to be stamped with the mark of inspection until
5 official import inspection has been completed and the product
6 is passed.

7 In the past a product could be what we call "pre-
8 stamped" provided it is maintained under certain controls and
9 then if passed import inspection, could enter commerce. This
10 avoided double handling of product by importers. The problem
11 is that because of the lack of good control on refused-entry
12 product, this led to some problems and at certain times,
13 evidently, in clandestine fashion under criminal activity, some
14 of the product was marked U.S. inspected and passed after being
15 refused entry and was moved into the country.

16 There is, as we all know, a grand jury now sitting
17 in Miami, and we understand that they will be issuing indict-
18 ments shortly regarding some of the criminal activity that's
19 been under investigation at that port now for about the last
20 year.

21 The instructions also reiterate the regulatory
22 requirement that refused-entry product must be disposed of
23 within 30 days after notice is given to the Director of Customs
24 of the rejection. Under the instructions, extensions may be
25 granted in emergency situations only and through my office.

1 If refused-entry product is not exported or otherwise disposed
2 of within the specified time, we will request legal action
3 through the Office of the General Counsel to destroy the
4 product for human food.

5 Under the new procedures, we will continue to
6 notify Customs when a shipment has been refused entry and also
7 when the product has been exported or otherwise disposed of.
8 Meat inspection officials of the country of origin are being
9 notified as well when products are found unacceptable, and the
10 reasons for the findings. They are also cautioned against
11 repeat violations. F.S.I.S. is also working closely with the
12 Customs Service to identify rapidly and resolve problems con-
13 cerning areas of overlapping jurisdiction and responsibility.

14 In a 1981 review of various U.S. ports of entry,
15 the Department's Office of the Inspector General identified
16 several problems in the meat sample selection and security
17 process which could result in questionable product being
18 introduced into consumer channels. Their review also uncovered
19 considerable delays between the time meat samples are col-
20 lected and are received by an F.S.I.S. laboratory for analysis.

21 To improve this process, we are giving special
22 attention to meat sampling procedures used at high-volume
23 import stations, where problems such as errors in sample
24 selection and identification are most likely to occur. We are
25 surveying sample security areas, especially where samples must

1 be held overnight, and will require security improvements
2 where facilities do not effectively prevent unauthorized access.
3 Wherever practicable, supervisors are conducting unannounced
4 reviews of sample security procedures and facilities.

5 We have taken several steps to improve sample
6 turnaround time. A review of the field laboratories' workload
7 has already resulted in an improved workload distribution. In
8 addition, inspectors will soon be provided instructions that
9 clarify sample shipment procedures, with particular emphasis
10 on weekend mail service. Finally, the laboratory computer
11 system now provides the regional inspection offices with a
12 weekly list of samples held in establishments longer than
13 three working days and samples in transit longer than seven
14 days.

15 In recent years we have made some notable improve-
16 ments in the residue program for imported meat. Although we
17 continue to detect violative residues in product from some
18 countries, we are finding that most countries are consistently
19 in compliance. This is due in part to cooperative efforts
20 between foreign governments and the United States which con-
21 tinue to improve detection and control procedures used by the
22 exporting countries before product leave their shores.

23 In addition to the increased emphasis on residues,
24 we have also been using more stringent follow-up testing for
25 product from firms whose prior shipments had violative residue

1 levels. That is, more samples are being taken on more lots
2 before a violative firm is returned to a normal sampling
3 schedule. Further we no longer accept, as a substitute for
4 testing, results of foreign pretests or certificates from
5 foreign governments certifying the residue levels of the
6 product.

7 Before I take questions on that particular area,
8 let me make just a few comments about exports and then we'll
9 cover those areas jointly.

10 EXPORTS

11 I would like to mentioned some current activities
12 and issues in the area of U.S. exports of meat and poultry
13 products to other countries.

14 For the past several years there have been ongoing
15 discussions with members of the European Economic Community,
16 currently comprised of ten nations, concerning E.E.C. import
17 regulations which are at considerable variance with those of
18 U.S.D.A. E.E.C. requirements for red meat exports, as spelled
19 out in a red meat directive issued several years ago, impose
20 burdens on U.S. exporters which we do not believe we should
21 have to meet, primarily because of the refinements which have
22 been built into the U.S. inspection system over the years,
23 and because the animals brought to slaughter here are
24 generally younger and healthier than their European counter-
25 parts, whereas in Europe much more emphasis is placed on

1 animal health activities.

2 Recent discussions with E.E.C. officials have
3 resulted in a proposal by the E.E.C. of a revision of the
4 existing red meat directive which would be much more favorable
5 to our position because it clearly recognizes the principle
6 of equivalence: the acceptance of alternative procedures that
7 achieve the same ends. The proposed revision is now proceeding
8 through a ratification process in the E.E.C. Council; unanimous
9 approval is necessary. In the meantime, E.E.C. members can
10 elect not to enforce the existing directive literally, although
11 West Germany in particular has insisted so far on doing so.

12 At present, there is no E.E.C. directive covering
13 U.S. poultry exports. U.S.D.A. is, however, encouraging the
14 development of a directive for poultry which embodies the
15 principle of equivalence.

16 Another matter of concern, both to the Food and
17 Drug Administration and to U.S.D.A., is the possibility of the
18 imposition by the E.E.C. of extremely stringent restrictions,
19 or even a total ban, on the use of hormones. Some of the
20 hormones in question are in wide use in this country. Although
21 we have explained at length in discussions with the E.E.C.
22 why we believe the current system of hormone controls is
23 adequate to protect the public health, it appears likely that
24 a ban will ultimately be issued and that enforcement will be
25 left to individual E.E.C. members, which of course would mean

1 coping with varying procedures.

2 We are also working to resolve some problems with
3 the United Kingdom concerning export of U.S. poultry products.
4 In 1980 the United Kingdom stipulated that all uncooked
5 poultry imports must originate in E.E.C.-certified plants, and
6 in 1981 all cooked poultry exports also became subject to this
7 requirement. Use of the counterflow chilling system is a key
8 requirement of E.E.C. certification, and only a few U.S.
9 plants can comply. Those that can must substantially increase
10 their water consumption and disposal requirements.

11 Another problem is the ban imposed by the United
12 Kingdom last year on imports of uncooked poultry from any
13 country where Newcastle disease existed or whose producers
14 inoculated their birds with Newcastle vaccine containing live
15 viruses. This action halted the annual export of approximately
16 6 million pounds of uncooked poultry from the United States to
17 the United Kingdom. This month, however, a European court
18 ruled against the United Kingdom's decision, but the effect of
19 the court's action remains to be seen.

20 In recent months members of the Export Coordination
21 staff of F.S.I.S. and others from U.S.D.A. including
22 Assistant Secretary McMillan on the latest European mission,
23 have traveled extensively to discuss issues associated with
24 export requirements. In April and May discussions were held
25 in the Middle East with officials of seven countries so that

1 we could gain a clear understanding of the export requirements
2 of these nations, which are now seen as potentially large
3 markets for U.S. meat and poultry exports.

4 In the Far East, export requirements were discussed
5 with authorities in Japan, Hong Kong, and Singapore.

6 It is clear that while a number of problems remain
7 to be resolved, progress is indeed being made through efforts
8 to emphasize and encourage the export of U.S. agriculture
9 products. Both F.S.I.S. and the Foreign Agricultural Service
10 continue to work diligently to identify new markets, to reach
11 resolution of problems arising from the divergence of in-
12 spection regulations, and to provide relief from non-tariff
13 trade barriers and regulatory burdens.

14 I would say, however, that we're still encountering
15 a lot of difficulty and we continue to believe that many of
16 the requirements that are established in the E.E.C., and the
17 fact that they can be selectively enforced, are being used
18 as trade barriers.

19 While I won't go into the common agricultural
20 policies of the E.E.C., they are certainly restrictive to the
21 U.S. and in our ability to get more of our agricultural
22 products into other markets.

23 We are very efficient producers of agricultural
24 commodities, more efficient than many other countries; but as
25 long as these barriers exist and the subsidies are paid by

1 our competitors, it's going to be difficult for us to maintain
2 some markets or enter others.

3 Let me open that area now of both imports and
4 exports to any questions of clarification at this point.

5 DR. FOSTER: I'm not sure this is a matter of
6 clarification, but I did notice that in your initial slide,
7 one of your first slides, a substantial amount of imported
8 meat from Denmark. Could you give us a brief word or two
9 about the situation on the foot-and-mouth disease and how it's
10 affected the importation.

11 DR. HOUSTON: There were some fresh pork products,
12 in fact, Denmark was starting to build a rather substantial
13 market in the United States with fresh pork products. Those
14 shipments stopped immediately. I think in the last full
15 year prior to the outbreak of foot-and-mouth disease they
16 brought in some 25 million pounds of fresh products and about
17 65 million pounds of canned products, canned cured products.

18 That does not affect their trade in canned cured
19 products because they are heat treated and therefore the virus
20 is destroyed and we have no concern there, provided they bring
21 it to a certain temperature.

22 So from that standpoint it has affected the trade
23 of fresh meat but not canned cured products.

24 We have been informed that the country of Denmark
25 considers themselves now rid of foot-and-mouth disease, their

1 eradication procedures have been put into place. But it's the
2 policy of U.S.D.A. however not to consider designating any
3 country foot-and-mouth free for at least one year following an
4 outbreak. During that period, there will be a close
5 evaluation of those procedures that were used to determine
6 that an outbreak has, in fact, been brought under control.
7 It also offers a time barrier in case there's any latent
8 problem that would surface so that we would not have product
9 coming into the United States and endangering our own live-
10 stock population.

11 Dr. Alfin-Slater.

12 DR. ALFIN-SLATER: Are the requirements for
13 imported products, the summary sheet, you have a statement
14 that "the proposed rule would amend the Federal meat inspection
15 regulations to clarify that the inspection sanitation quality,
16 etc. parts of carcasses of meat and meat food products of
17 cattle, sheep, swine, goats, horses, mules, and other species,
18 etc., must be at least equal to the standards applied to such
19 domestic products produced in the United States."

20 Do we have standards for mules and kangaroos and
21 buffalo?

22 I think that's a little ambiguous because they can
23 say, "Well, you don't have these standards and so we can use
24 our own standards."

25 DR. HOUSTON: We apply our standards against a

1 country who would ship products here. We do have standards
2 for all the domestic species, and we obviously don't have any
3 for kangaroo. We do have standards for animals in the United
4 States that we inspect on a fee basis that are not subject to
5 the Federal Meat Inspection Act, such as buffalo and reindeer.
6 We have standards for horses; there are 16 plants that slaughter
7 horses in the United States, which slaughter about 300,000
8 horses a year, the vast majority of which are shipped to
9 Europe. Very little horse meat is consumed in the United
10 States, but it's consumed in rather large amounts in Europe.

11 So we do have all those standards, and those
12 standards would be applied against any country who wished to
13 ship product here.

14 DR. ALFIN-SLATER: I'm just saying, you don't have
15 standards for kangaroos, and suppose Australia says, "Well,
16 we have our own standards and so you accept these because you
17 don't have any standards."

18 DR. HOUSTON: Species that are not specifically
19 identified and there's a mistake in there. As you read it
20 I see where it states "and others," and that should not be in
21 there.

22 That should have been limited just to the species
23 that are identified in the Federal Meat Inspection Act, which
24 are cows and horses and goats and sheep, and so forth.

25 DR. ALFIN-SLATER: Okay. I feel better.

1 DR. HOUSTON: Any other exotic meat coming into the
2 United States is free to enter but is subject to the Food and
3 Drug Act. F.D.A. has jurisdiction over all exotic meat that
4 comes in, and it does come in. Kangaroo comes in, lion meat
5 comes in, rhinoceros comes in, snake meat is in interstate com-
6 merce. There are a number of restaurants around the country
7 that cater to clientele that want these foods. In fact, there's
8 one restaurant in Washington D.C. that each week has a
9 speciality, and I noticed in the paper several weeks ago it
10 was kangaroo. One week it's lion meat, so on and so forth.

11 DR. ALFIN-SLATER: I'm glad that's Washington.

12 How are we sure that we are protected against
13 Lord knows what that might come in with the meat?

14 DR. HOUSTON: Regarding the meats that are under our juris-
15 diction, we of course go right back to the country of origin
16 to be sure that the inspection system is equal to ours, and
17 then we reinspect the product when it enters this country.

18 F.D.A. does not have that intensive of a program,
19 and they pretty much rely on some system of inspection at
20 ports of entry. I'm not really that familiar with how in-
21 tensive an inspection they're carrying out on those products.
22 But that is under their jurisdiction. I really can't deal
23 with that in terms of what they're doing with those products.

24 Rabbits are also coming into this country. They're
25 not subject to the Federal Meat Inspection Act. There's very

1 substantial amounts coming in from China, People's Republic of
2 China and Australia. I know that F.D.A. has become quite
3 concerned about that and has conducted more intensive
4 inspection of those products.

5 Dr. Foster.

6 DR. FOSTER: Yes. I might just add that F.D.A.
7 also is responsible for frog legs, and they have been very
8 careful about insisting that the frog legs imported be free
9 of salmonella, for example. They inspect them at the port;
10 they sample them; and they reject them very frequently.

11 DR. HOUSTON: I don't want to leave the impli-
12 cation that F.D.A. is not doing anything in this area. It's
13 simply that I'm not familiar enough with their procedures to
14 tell you how many lots they're looking at, so on and so forth.

15 MR. LOUNSBERRY: That would have to be specific
16 kinds of salmonella, I assume. They surely aren't geared up
17 to test for all types of salmonella in frog legs. How many
18 types of salmonella are there? How many thousands of types of
19 salmonella are there?

20 DR. FOSTER: About 1,800. They test for everyone
21 of them.

22 MR. LOUNSBERRY: They do?

23 DR. FOSTER: Sure. They might not identify
24 specifically which sero type.

25 MR. LOUNSBERRY: Well, I haven't seen Food and

1 Drug labs that have the capability, the ones I've seen haven't,
2 anyway.

3 DR. HOUSTON: I believe there probably are some
4 screening procedures available that will identify that species
5 without identifying sero types.

6 DR. FOSTER: They don't necessarily identify the
7 sero type. They just know that the genus is there, and that's
8 enough as far as they're concerned.

9 DR. HOUSTON: Any other points in the area of
10 import and export?

11 MR. MC DADE: This proposed regulation that we
12 have here is very brief. Now the points that you discussed
13 that were going to be put into effect, is that going to be
14 done administratively? I'm trying to tie together what you
15 read to me and what I have here.

16 DR. HOUSTON: What you have is the proposed rule
17 as a result of the 1981 Farm Bill. That codifies existing
18 administrative policy. In addition I pointed out a number of
19 things that we're doing administratively that go far beyond
20 what's required in the Farm Bill. In terms of looking, for
21 example, at a country's total regulatory system, outside of
22 plants for example, as well as some of the tightening up
23 procedures at the port of entry here.

24 MR. MC DADE: I was just trying to find out if
25 that was different, and if so, how.

1 DR. HOUSTON: It's an addition to that.

2 MR. MC DADE: Thank you.

3 DR. BURNETTE: Don, appreciate your update on the
4 export situation and particular the E.E.C. rules. I know some
5 of the frustrations of administration policy.

6 I'm at a loss to figure out what this Committee
7 could look at or could do or could even talk about on export
8 policy since it's totally disconnected from the negotiation
9 process. If there was something there specifically we're sup-
10 pose to be thinking about other than just receiving the update,
11 I didn't understand it.

12 DR. HOUSTON: I did want you to be aware of where
13 we stood. I wanted you to be aware that we are pushing this
14 matter of equivalence. When you get into trade, it's a two-
15 way street. We like to think it's a two-way street. Sometimes
16 it isn't. But if we push the matter of equivalence, we've got
17 to treat our trading partners in the same vein.

18 Another thing to keep in mind is that any time we
19 change our law, that automatically has an effect on other
20 countries as well. For example if we were to change our law
21 and go to discretionary processing inspection, we'd have to
22 look at other systems in the same light. We couldn't ask them
23 to impose tighter standards than we are.

24 DR. BURNETTE: That's one of the reasons that I
25 asked the question about the Codex Standards earlier on

1 margarine, because that's a very sensitive issue. Where we
2 already have standards, if we refuse to examine the Codex
3 Standards when they come out, then the E.E.C. is going to beat
4 us over the head with them when we go back with our poultry.

5 DR. HOUSTON: Yes, you're right.

6 Does anyone else have a comment to make or a
7 question of clarification?

8 Okay. We're on schedule. It's 4:30.

9 FOOD SAFETY LEGISLATION

10 Next is a quick update on Food Safety legislation.
11 I reported to you when we last met that the White House Working
12 Group on Food Safety, chaired by Bill McMillan, had given its
13 proposals for changes in the food safety laws to the Cabinet
14 Council on Human Resources, whose responsibility it is to
15 develop the Administration's position on changes in those laws.
16 The Cabinet Council has since that time made the Working
17 Group's proposals public and it has asked the Group to consider
18 the comments of consumer, industry, and scientific organizations
19 before it makes its final recommendations to the Council. The
20 Working Group is now in the process of interacting with those
21 organizations to evaluate its proposals and, where appropriate,
22 to incorporate the ideas of these groups into its suggested
23 statutory language.

24 I might add that we completed one round of discus-
25 sions with these groups. We have considered those comments,

1 and we are now planning the second round of discussions with
2 the affected parties to begin within the next several weeks.
3 If everything goes well, we will then submit our final recom-
4 mendation for the Administration position to the Cabinet
5 Council on Human Resources.

6 The package you have received for this meeting con-
7 tains a summary of the Working Group's report. I thought you
8 might be interested in my views on the nature and significance
9 of the proposals contained in that report. First let me run
10 through some of the more interesting proposals for you and
11 point out why the group chose to make these particular
12 recommendations.

13 The Working Group has suggested that a new
14 regulatory category for traditional foods be created. The
15 purpose of this change is to clarify in the statute Congress's
16 intention that foods with a long history of use in this
17 country be subjected to more lenient safety standards than
18 food additives that do not have this kind of experience behind
19 them. This would help to avoid the possibility that a
20 regulatory agency would have to take precipitous action
21 against a food that has become a staple of our food supply.

22 The Working Group has suggested the statute incor-
23 porate a definition of "safe" which makes clear that the safety
24 objectives in the law are not based on the pursuit of zero
25 risk. The Working Group believes that the definition it

1 proposes reflects the objectives under which the law is cur-
2 rently administered.

3 The Working Group's suggestion for phaseout
4 authority introduces a new concept into food safety law. This
5 authority would permit regulatory agencies to take a longer
6 time to eliminate a produce that must be prohibited from the
7 market if such gradual elimination does not pose an immediate
8 risk. Agencies are presently not permitted to do this, and
9 the problems of not having this authority became apparent
10 when the possibility that nitrite would have to be removed
11 from the market was encountered. The Working Group has sug-
12 gested that the administration of phaseout authority is the
13 appropriate place, and the only place, in the law where non-
14 health factors such as severe disruption of the food supply
15 and economic hardship should be considered.

16 The Working Group has recommended that the statute
17 be modified so that contemporary science can contribute to the
18 evaluation of a substance as a possible carcinogen. This
19 would maintain the current policy, reflected in the Delaney
20 clause, that human carcinogens are not permitted in the food
21 supply. At the same time it would give regulators more
22 flexibility in distinguishing a human from an animal carcinogen.

23 The Working Group has also recommended that the law
24 permit risk assessment procedures to be used when determining
25 whether or not a carcinogenic animal drug may be used in

1 producing animals whose tissues are used for human food.

2 The Working Group has suggested that the procedures
3 and criteria for regulating certain kinds of indirect additives
4 used for packaging be modified to reflect their low public
5 health risk status. The purpose of this change in the law
6 would be to reduce the excessive burden on both the agencies
7 and industry associated with regulating packaging materials
8 which have constituted a large portion of the regulatory burden
9 in recent years. F.D.A. has recently announced a proposal
10 known as the constituents policy, which is designed to permit
11 scientific evaluation of carcinogenic additives when they are
12 present in minute amounts, having migrated into food products
13 from packaging. The Working Group's proposals on indirect
14 additives would complement the constituents policy.

15 The Working Group has suggested that net health
16 benefits be considered when deciding on the disposition of a
17 hazardous substance, even if it is a carcinogen. The
18 rationale for this position is that the food safety laws are
19 public health statutes, and it therefore makes no sense, for
20 example, to ban a substance if the resulting health effects
21 are more hazardous to human health than the ones that have
22 been avoided.

23 The Working Group has recommended that product-by-
24 product approval for some establishments using medicated feeds
25 be replaced by a one-time registration. The purpose of this

1 proposal is to permit regulatory resources to be allocated to
2 the higher-risk problems of the medicated feed sector, that is,
3 those places where the first dilutions of animal drugs occur.

4 The Working Group recommended that U.S.D.A. be
5 given authority to set tolerances for pesticides in food
6 products when other agencies do not set the tolerances. This
7 will enable U.S.D.A. to deal in a timely fashion with some of
8 its regulatory emergencies, and will permit public partici-
9 pation in the setting of regulatory limits, which has not been
10 the case when U.S.D.A. has had to operate under action levels
11 set by other agencies.

12 In addition to the proposals described above, the
13 Working Group has recommended a number of other measures that
14 would help streamline the regulatory process, such as in the
15 evaluation of incidental additives found in packaging materials.

16 If I had to characterize the Working Group's effort
17 in a few words, I would say that it is designed to make the
18 food safety laws more workable in today's environment,
19 especially with respect to the utilization of the scientific
20 advancements that underlie our ability to produce and analyze
21 new food products. An important aspect of this effort has
22 been an attempt to allocate government and industry resources
23 to the food safety areas of the greatest concern. I believe
24 it is unlikely that any of the proposals I have described will
25 generate significant changes in the day-to-day administration

1 of our regulatory programs at U.S.D.A., however, they would of
2 course have a great impact on the regulatory process at F.D.A.
3 especially in regard to evaluation of food additives.

4 The Working Group's activities, which are designed
5 to help the Cabinet Council establish an Administration position
6 on food safety, are continuing. To assure consistency in
7 regulation across agency lines, F.D.A. and U.S.D.A. are working
8 together as a team in the effort to include ideas from the
9 public in our report. We have had productive discussions with
10 various industry groups in order to better understand the
11 objectives on all sides and to work out language that will
12 reflect as much as possible our common objectives.

13 It has been heartening for me to realize as a
14 result of this process how large a common ground the regulator
15 and the industry share in our attempts to assure that our food
16 supply is safe. Disagreements reflect not a difference of
17 basic objectives, but a difference as to who should bear the
18 burden when uncertainty arises in the regulatory process. The
19 Working Group sees its responsibility as being one to assure
20 that the public health does not bear that burden. At the
21 same time, it is attempting to improve the regulatory process
22 so that unnecessary burdens are not placed on industry where
23 the public health is not at risk.

24 Any questions?

25 Dr. Foster.

1 DR. FOSTER: Generally I've heard two comments
2 about this document. One of them was about six weeks ago,
3 five weeks ago, by a prominent Washington lawyer, former
4 important high government official in the food safety area,
5 said this document is distinguished by the fact that everybody
6 is against it. I rather doubt that but I wanted to here what
7 you would say in response.

8 Before I do that, I would like to clarify another
9 point. I've also heard that this document would eliminate the
10 GRAS status. I don't see any evidence of that. Am I wrong
11 or have I been misinformed?

12 DR. HOUSTON: Let me answer your first question.

13 I recall reading that comment by the prominent
14 Washington attorney and former member of the Food and Drug
15 Administration. I simply don't share his attitude, and I
16 think other people would agree with me. However, I suppose,
17 well, I won't go any further than that at this point.

18 This would eliminate GRAS, post '58. But we've
19 carefully looked at that whole GRAS situation during this
20 comment period. While I do not want to make any comments at
21 this point, we're carefully considering making some modifi-
22 cations in that area. Without stating what those might be,
23 I'll just say that we're aware of the concerns that have been
24 expressed about that and considering some modifications.

25 DR. FOSTER: Thank you.

1 MRS. CRAMER: Would you go over again the makeup
2 of the Working Group?

3 DR. HOUSTON: Yes. The Working Group is chaired by
4 Assistant Secretary Bill McMillan from U.S.D.A., it's composed
5 of Assistant Secretary for Health, Ed Brandt from H.H.S., .
6 Commissioner Arthur Hayes from Food and Drug Administration,
7 the Deputy Administrator of the Environmental Protection Agency,
8 John Hernandez, and myself. We also have an ex officio member,
9 Mr. Burley Leonard from the White House, who is on the Senior
10 Policy Staff at the White House and participates in the
11 deliberations of the Working Group.

12 Dr. Whelan.

13 DR. WHELAN: As you know in the last year a number
14 of bills have been introduced to Congress to change the food
15 safety laws, Hatch, Wampler and others.

16 How does your document relate to proposed legis-
17 lation that may come in the next session? Will this be called
18 upon as an expert support document, or will it ever actually
19 be part of some new legislation that maybe proposed?

20 DR. HOUSTON: You're right. There's been the
21 Hatch bill, the Gore bill, then there's been the so-called
22 Kennedy-Hatch-Staff proposal, and of course there's our pro-
23 posal, the Working Group's proposal, with specific language.

24 We started out as a Working Group following the
25 introduction of the Hatch bill last year. We used that as a

1 basis for much of our evaluation. In addition we went into
2 other areas beyond which the Hatch bill covered. I'd say we're
3 right in line with the same areas that are covered in the
4 Hatch bill, as well as the Gore bill. We suggest some
5 modifications from the Hatch bill and Gore bill, and when we
6 put those out for informal comment, of course there were a
7 lot of people who disagreed with the way we went in terms of
8 looking at it through the Hatch bill.

9 Nevertheless, we've taken all those comments into
10 consideration, and as I said, we do have modifications under
11 consideration. I think it would be premature for me to make
12 any statements as to what those modifications will be. I think
13 that's up to the Chairman of the Working Group to discuss it
14 with the Cabinet Council before those are put out for further
15 comment.

16 But I would expect that the areas that have been
17 put in the Hatch act for modification are the same areas that
18 are in the Working Group. Once the Cabinet Council accepts
19 them, that will become the Administration's position on food
20 safety and will serve as the basis for hearings, for development
21 of testimony, and perhaps even the development of a bill. It
22 could even move that far, although it could be limited just to
23 hearings at this point.

24 Just to reiterate, we believe that will become
25 the Administration position on food safety.

1 It has to be accepted by the Cabinet Council, and
2 of course it has to be accepted by the White House. The
3 Cabinet Council on Human Resources is a Cabinet-level council
4 and works through the aegis of the White House. So I think
5 if we get it that far, it'll be in pretty good shape.

6 DR. BURNETTE: Who is on the Cabinet Council
7 besides Block and Schweicker?

8 DR. HOUSTON: Well, O.M.B. has a seat; Labor has
9 a seat. I don't recall the other members of that Cabinet
10 Council, I'm sorry. But I do know Labor and O.M.B. have a
11 seat, and H.H.S., and Agriculture is on it for the purposes
12 of food safety policy.

13 Any other questions?

14 MR. CRAIG: At what point precisely do you get
15 effective input from, in this case, the consumer and the
16 industry on matters of this type where you're shaping a far-
17 reaching policy? The establishment or maybe we should say
18 the building of a house, then once you get the house built,
19 or maybe you would say designed, it gets potshot at by the
20 consumer and the industry.

21 DR. HOUSTON: At this point we've done it on an
22 informal basis by testing the water, if you will, by putting
23 out the first round of recommendations that were developed
24 last year to a whole range of affected parties, principally
25 industry and trade groups, but also consumer groups.

1 I might say that the consumer groups were pretty
2 much opposed to any change. They believe that the present
3 law should remain as written, and that they see no need for
4 change. Other groups do see some need, industry groups. We
5 also talked with a number of scientific organizations. Most
6 of them agree some change is needed.

7 We've taken those comments we've gotten so far and
8 are reshaping some of the language at this time. We will take
9 that to the Cabinet Council and if there's substantial agree-
10 ment, we'll move out and have another
11 round of discussions with affected parties, and then probably
12 go with a final set of recommendations.

13 Keep in mind that what we're trying to do is
14 achieve as much consensus as we can at this point knowing
15 full well that everyone will still have the opportunity to
16 make their viewpoints known during Congressional hearings.
17 In the final analysis it's the Congress that will decide what
18 that language will be. We've used a rather informal approach
19 thus far, I would say.

20 DR. BURNETTE: Do you have with you, because I
21 don't think the group is aware of the breadth of the three
22 briefings and the extent of the three briefings that were held
23 in what you call an informal proceeding but it was of rather
24 extensive magnitude. Do you have the list of the people who
25 participated in that with you?

1 DR. HOUSTON: No, I don't, but it was very
2 extensive.

3 DR. BURNETTE: Let me say because I participated
4 in one of them, just pertaining to your question, Frank, from
5 the scientific societies I would guess there were at least
6 25 societies invited, everyone from the American Association
7 for the Advancement of Science and the American Chemical
8 Society to the Institute of Food Technologists, the Society of
9 Toxicologists, all of the affected scientific organizations.

10 The same procedure was followed for consumer
11 groups and for trade association groups. A lot of people got
12 full briefings by the Working Group, and an opportunity to
13 file written comments, which have been fairly extensively
14 covered in Food Chemical News over the last couple of weeks.

15 DR. HOUSTON: Any other questions?

16 FOOD SAFETY POSTER CONTEST

17 You've been provided with some background infor-
18 mation on the F.S.I.S. National Food Safety Poster Contest,
19 but I'd like, first, to give you more details about the
20 direction we will be taking for next year's contest and,
21 secondly, to tell you something about other efforts to educate
22 consumers about food safety and nutrition.

23 The first two poster contests focused on safe
24 handling of food. I don't have the actual number of partici-
25 pants that were involved in those contests. I think it's in

1 the information that was sent to you, but they were both very
2 successful. Thousands of young people got involved in these
3 food safety poster contests.

4 Next year the theme will be food labeling, with
5 the emphasis on being a well-informed consumer. The contest
6 kits which will be mailed to schools nationwide will include
7 information on aspects of Federal labeling regulations and
8 related food safety requirements. There will be descriptions
9 of the kinds of nutritional, identifying, and handling infor-
10 mation that appears on modern food package labels and an
11 explanation of how this information can be used from health,
12 safety, and economic standpoints. In addition, emphasis will
13 be placed on safe buying practices, such as avoiding bulging
14 or severely damaged cans, and making meat and poultry purchases
15 last.

16 I would say here that this is a more sophisticated
17 subject than we've gone into in the past, and we will probably
18 not have next year's in the kindergarten, first grade area.
19 The experts in this area have indicated that we probably ought
20 to limit this to the second through sixth grade because of
21 the complexity associated with the subject of food labeling.

22 Since we are in the preliminary planning stage for
23 the 1983 contest, any suggestions you have concerning other
24 aspects of food labeling which could be covered or regarding
25 our approach would certainly be welcomed. I would also very

1 much appreciate your suggestions of subjects which could be
2 themes for future poster contests.

3 In addition to the poster contest, which is aimed
4 at educating the young consumer, F.S.I.S. is involved in a
5 number of other activities designed to educate the public on
6 the care, handling, composition, inspection, and labeling of
7 food products.

8 There are currently 19 F.S.I.S. publications con-
9 cerning food safety and nutrition. Single copies of publi-
10 cations are free, and bulk copies can also be provided at no
11 charge to most organizations. A list of these educational
12 publications has been given to each of you.

13 We also produce educational audiovisual material:
14 radio and television public service announcements, slide
15 shows, and exhibits. To publicize the availability of publi-
16 cations and audiovisual material, the Agency's public aware-
17 ness and information staffs use direct mail campaigns, press
18 releases and other notices to the media, and items in the
19 F.S.I.S. newsletter "Food News for Consumers," as well as
20 public service announcements. In addition, information and
21 public awareness staff members attend conferences, such as
22 those of the American Dietetic Association and the American
23 Public Health Association, to bring our educational material
24 to the attention of the groups' members.

25 The Consumer Information Center, which is the

1 distribution point for government-issued consumer information,
2 lists several F.S.I.S. publications in its catalogue, and mail
3 thousands of copies of these each year to interested con-
4 sumers.

5 A current example of an F.S.I.S. food information
6 campaign is our effort to publicize the brochure entitled
7 "Sodium -- Think About It," which we talked about earlier and
8 which you each have a copy.

9 In early June nearly 1,000 letters were mailed to
10 Members of Congress, trade associations, consumer and pro-
11 fessional organizations, newspapers, magazines, and Federal,
12 State and local government offices to announce publication of
13 the sodium brochure. At present a series of television and
14 radio announcements is being prepared to promote the brochure.

15 Requests for thousands of copies of the sodium
16 brochure and for sets of negatives to be used to reproduce it
17 have been received. Another very popular publication in
18 recent months is the one called "Summertime Food Safety,"
19 which has been sent to hundreds of schools and organizations.

20 If any of you have ideas for future food safety
21 campaigns or suggestions of subjects which could be covered
22 in educational publications or public service announcements,
23 please let the Agency know. As I mentioned, I would also
24 appreciate your ideas for the Food Safety Poster Contest.

25 Are there any questions on that?

1 There being none, we will proceed to ask if there
2 are any members from the public today who would like to raise
3 any questions or make any statements before we adjourn the
4 meeting?

5 Are there any other questions from the Committee
6 before we adjourn?

7 MR. MC DADE: Do we have any arrangements on
8 checking out tomorrow? Do we have a noon or 2 o'clock check-
9 out, or should we bring our bags down here tomorrow morning?
10 Does anybody know?

11 DR. HOUSTON: We'll notify you tomorrow morning
12 early of that requirement. Perhaps we can even find out this
13 evening and let you know.

14 MR. MC DADE: Thank you.

15 DR. ALFIN-SLATER: Checkout is 1 o'clock, they
16 told me.

17 DR. BURNETTE: Can I modify the question?

18 DR. HOUSTON: Yes.

19 DR. BURNETTE: Those of us going all the way back
20 to the East Coast have two choices: a late redeye or stay
21 over until Saturday. It would be convenience I know for myself
22 and George, at least, if we could get a very late checkout, or
23 extended half a day or something, so that we have some place
24 to be until midnight when we have to catch a plane.

25 DR. HOUSTON: I happened to read the rules posted

1 on my door, and I think it says that either 11 o'clock or
2 1 o'clock is checkout time. You can stay until 6 o'clock at
3 half rate, I think or reduced rate. After 6 o'clock it
4 is the full rate.

5 Unless we can do something further to help, that's
6 what I've been told at this point.

7 Dr. Whelan.

8 DR. WHELAN: What are the plans for the meeting
9 tomorrow? Are we going to go from 9:00 straight through? Is
10 there going to be a lunch break? What is the procedure?

11 DR. HOUSTON: I think we'll play that by ear.
12 We'll open up and go through the same agenda again and ask for
13 any observations, comments, statements that the individual
14 members want to make. Sometimes we get into colloquy. Some-
15 times there's discussion between various members of the Com-
16 mittee, and I hesitate to break that discussion off. I'd like
17 to be as complete as possible. However if we move through
18 these rather quickly, in the past the Committee has chosen to
19 work through the lunch period and perhaps finish up maybe at
20 1 o'clock or early in the afternoon, rather than take that
21 lunch period and go on.

22 So we'll watch in the morning. If we move through
23 these rather quickly, we have that option available to us.

24 If the discussion carries on and there's a lot of
25 interest in some of these, it maybe to the best advantage, at

1 least to the majority, to take the lunch break and then come
2 back and spend the afternoon.

3 I'm sorry I can't give you a definite answer.

4 DR. ALFIN-SLATER: Do we meet here tomorrow in
5 this room?

6 DR. HOUSTON: Tomorrow morning at 9 o'clock, yes.

7 DR. ALFIN-SLATER: Can we leave things here or not?

8 DR. HOUSTON: I don't think we should.

9 The meeting is adjourned until 9 o'clock tomorrow
10 morning.

11 (Whereupon at 4:55 p.m. Thursday, July 29, 1982,
12 the Advisory Committee meeting was adjourned
13 until 9 o'clock on Friday, July 30, 1982.)

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C E R T I F I C A T I O N

This is to certify that the attached proceedings
before the UNITED STATES DEPARTMENT OF AGRICULTURE, in the
matter of the ADVISORY COMMITTEE ON MEAT AND POULTRY INSPECTION,
on Thursday, July 29, 1982, at The Sheraton-Palace Hotel,
Comstock Room, 639 Market Street, San Francisco, California,
were had as therein appears, and that this is the original
transcript thereto for the files of the DEPARTMENT OF
AGRICULTURE.

Kay Damgaard



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